PRIOR AUTHORIZATION CRITERIA

This is a complete list of drugs that have written coverage determination policies. Drugs on this list do not indicate that this particular drug will be covered under your medical or prescription drug benefit. Please verify drug coverage by checking your formulary and member handbook. Additional restrictions and exclusions may apply. If you have questions, please contact Providence Health Plan Customer Service at 503-574-7500 or 1-800-878-4445 (TTY: 711). Service is available five days a week, Monday through Friday, between 8 a.m. and 6 p.m.

ACIPHEX SPRINKLE/DELIXANT/ESOMEPRAZOLE STRONTIUM CAPSULES/NEXIUM

MEDICATION(S)
DEXILANT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of an adequate trial and failure** of 2 of the following 3 options:
1. omeprazole 80mg daily (omeprazole 40mg twice-a-day)
2. lansoprazole 30mg twice-a-day
3. pantoprazole 80mg daily (40mg twice-a-day or 80mg once-a-day).

For Aciphex Sprinkle only
1. Documentation of an adequate trial and failure** of or contraindication to treatment with two formulary proton pump inhibitor medications

**An adequate trial is defined as documentation of taking the medication at the maximum dose for 10-days)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for up to one year
For Zollinger-Ellison syndrome: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A

ACTINIC KERATOSIS AGENTS

MEDICATION(S)
CARAC, FLUOROURACIL 0.5% CREAM, IMIQUIMOD 3.75% CREAM PUMP, PICATO, TOLAK, ZYCLARA

COVERED USES
N/A

EXCLUSION CRITERIA
• Treatment of pain
• Treatment of basal cell carcinoma or other skin cancers

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a dermatologist.

COVERAGE DURATION
Picato®/Tolak®/Carac®: Initial authorization and reauthorization will be approved for one month
Zyclara®: Initial authorization and reauthorization will be approved for up to 8 weeks

OTHER CRITERIA
1. For the treatment of Actinic Keratosis (AK):
Documentation of trial and failure*, contraindication or intolerance to two (2) of the following formulary, generic topical agents:
a. Diclofenac 3% gel
b. 5-fluorouracil 2% or 5% cream/solution
c. Imiquimod 5% cream

*An adequate trial and failure is defined as failure to achieve clearance of AK lesion(s) after adherence to recommended treatment dosing and duration (see Table 1)

Reauthorization:

Requires documentation of a reduction in the number and/or size of lesions of AK and medical rationale for continuing therapy beyond recommended treatment course (see Table 1).

2.For the treatment of external genital and perianal warts/condyloma acuminate (Zyclara® 3.75% only): Documentation of trial and failure*, contraindication, or intolerance to formulary, generic imiquimod 5% cream.

*An adequate trial and failure is defined as failure to achieve total clearance of lesions after 16 weeks of therapy.

Reauthorization:
Requires documentation of improvement of the condition with therapy.

ALBENZA, EMVERM

MEDICATION(S)
ALBENDAZOLE 200 MG TABLET, ALBENZA, EMVERM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
See “Other Criteria”

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 3 months.

OTHER CRITERIA
1. For the treatment of pinworms (Enterobius vermicularis):
o Documented trial, failure, intolerance, or contraindication to pyrantel pamoate (available over the counter)
OR
2. For diagnoses other than pinworm (Enterobius vermicularis), must be prescribed by or in consultation with an infectious disease specialist.*

*Requirement that therapy is prescribed by or in consultation with an infectious disease specialist maybe be waived if diagnosis has been confirmed through validated laboratory testing/identification

ALINIA

MEDICATION(S)
ALINIA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For diarrhea caused by Cryptosporidium parvum in patients without HIV and diarrhea caused by Giarda lamblia: authorization will be approved for 3 days.

For diarrhea caused by Cryptosporidium parvum in patients that are HIV positive: authorization will be approved for 14 days

OTHER CRITERIA
For diarrhea caused by Cryptosporidium:
1. Confirmed diagnosis of Cryptosporidium parvum
AND
2. For therapy greater than 3 days, up to 14 days: documentation that patient is HIV positive

For diarrhea caused by Giardia:
1. Confirmed diagnosis of Giardia
AND
2. Documentation of trial and failure, intolerance, or contraindication to tinidazole

QUANTITY LIMIT:

Nitazoxanide (Alinia®) 500 mg tablets: 6 tablets per day 30 days

Nitazoxanide (Alinia®) 100 mg/ 5 ml suspension: 150 ml per 30 days

AMIFAMPRIDINE

MEDICATION(S)
RUZURGI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization (all of the following must be met):
1. Confirmed diagnosis of Lambert-Eaton myasthenic syndrome (LEMS): AND
2. Documentation of confirmatory diagnostic test results including:
a. Repetitive Nerve Stimulation (RNS) testing showing reproducible post-exercise increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared with pre-exercise baseline value or a similar increment on high-frequency repetitive nerve stimulation without exercise OR
b. Positive anti-P/Q type voltage-gated calcium channel antibody test: AND
3. Documentation of clinical symptoms of LEMS, including dyspnea or functionally significant muscle weakness, that interferes with daily activities: AND
4. Member has been evaluated for malignancy and treated for malignancy, if present. Note: LEMS symptoms associated with malignancy may resolve after treatment directed at malignancy: AND
5. Documented trial (of at least 1 month) and failure or intolerance of pyridostigmine.
6. For Firdapse®: Documented trial and failure of Ruzurgi®
Reauthorization:
1. Documentation of improvement or stabilization of muscle weakness from baseline

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist

COVERAGE DURATION
Initial approval will be approved for 3 months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A

ANTIFUNGAL AGENTS

MEDICATION(S)
CRESEMBA 186 MG CAPSULE, ITRACONAZOLE 10 MG/ML SOLUTION, ITRACONAZOLE 100 MG CAPSULE, NOXAFIL 40 MG/ML SUSPENSION, NOXAFIL DR 100 MG TABLET, POSACONAZOLE, SPORANOX, VFEND, VORICONAZOLE 200 MG TABLET, VORICONAZOLE 40 MG/ML SUSP, VORICONAZOLE 50 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an infectious disease specialist, hematologist, oncologist, or pulmonologist for all indication except onychomycosis or dermatomycosis

COVERAGE DURATION
For prophylaxis of invasive Aspergillus or Candida infections: initial authorization and reauthorization will be approved for one year
For other covered uses: Initial authorization will be approved for 3 months. Reauthorization will be approved for up to one year.

OTHER CRITERIA
1. For oropharyngeal or esophageal candidiasis (itraconazole solution, posaconazole and voriconazole only):
a. For itraconazole solution: Documented failure, intolerance, or contraindication to fluconazole
b. For voriconazole or posaconazole: Documented failure, intolerance, or contraindication to fluconazole and itraconazole solution

Note: itraconazole capsules are not covered for this indication. Their use is not supported by Infectious

Diseases Society of America (IDSA) guidelines, as they were considered less effective than fluconazole

2. For the treatment of invasive Aspergillus or disseminated Candida infections:
a. Confirmed diagnosis (Fungal culture and other relevant laboratory studies [including histopathology] must be documented)
b. For posaconazole or isavuconazonium: Documented failure, intolerance, or contraindication to voriconazole

3. For the treatment of blastomycosis or histoplasmosis: itraconazole may be covered
a. For voriconazole: Documented failure, intolerance, or contraindication to itraconazole

Note: posaconazole is not covered for this indication

4. For prophylaxis of invasive Aspergillus or Candida infections (posaconazole or voriconazole): Patient is immunocompromised due to one of the following:
a. Hematopoietic stem cell transplant recipients with graft-versus-host disease
b. Current diagnosis of cancer currently undergoing chemotherapy or radiation
c. HIV/AIDS

5. For onychomycosis (itraconazole only):
a. Documented failure, intolerance, or contraindication to generic terbinafine
AND
b. One of the following criteria must be met:
i. Use is for an immunocompromised patient (e.g., current chemotherapy/radiation, HIV/AIDS)
ii. A fungal infection of the extremity in the presence of a severe circulatory disorder
iii. A diabetic and fungal state that poses significant risk unless treated with systemic antifungal therapy
iv. An infected nail that cannot be removed and leads to recurrent cellulitis (more than one episode)
v. Pain limiting normal activity

6. For dermatomycosis (itraconazole only):
a. Documentation that the treatment area is large enough or in multiple locations such that it is not practically treated with topical agents
AND
b. For Medicaid members only: Use is for an immunocompromised patient.

7. For treatment of mucormycosis: isavuconazonium may be covered.

8. For empiric antifungal therapy in patients with febrile neutropenia: itraconazole, voriconazole or posaconazole may be covered

For reauthorization: Documentation supporting continued use of the requested agent for the intended diagnosis (such as continued active disease, length of therapy is supported by literature or guidelines, for prophylaxis patient continues to be severely immunocompromised)

ANTIMALARIAL AGENTS: COARTEM, DARAPRIM

MEDICATION(S)
COARTEM, DARAPRIM, PYRIMETHAMINE 25 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
Use for prophylaxis against malaria

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For treatment of malaria or toxoplasmosios: authorization will be for 3 months
For prophylaxis against toxoplasmosis: Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA
For treatment of acute malaria:
1. Documentation of acute, uncomplicated infection caused from the species Plasmodium falciparum
2. Documentation that the infection was acquired in a chloroquine- or mefloquine-resistant area

For the treatment of toxoplasmosis (pyrimethamine only):
1. Documentation of Toxoplasma encephalitis infection in a pregnant or immunocompromised patient.
AND
2. Documentation that the patient will be using pyrimethamine with sulfadiazine, or clindamycin plus leucovorin if the patient cannot tolerate sulfadiazine

For the prevention of toxoplasmosis (pyrimethamine only):

1. Documentation that the patient has HIV with a CD4 count less than 100 cells/uL
AND
2. Documented intolerance or contraindication to prophylaxis with trimethoprim-sulfamethoxazole

For reauthorization: documentation that that the patient’s CD4 count remains below 200 cells/uL

APOKYN

MEDICATION(S)
APOKYN, KYNMOBI

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use with any of the 5HT3 receptor antagonists (e.g. ondansetron, granisetron, dolasetron, or palonosetron)

REQUIRED MEDICAL INFORMATION
1. Patient has Parkinson's disease and is experiencing acute intermittent hypomobility ("off" episodes) averaging at least 2 hours daily
AND
2. Patient is on other medications for the treatment of Parkinson's disease (e.g., carbidopa/levodopa, pramipexole, ropinirole, benztropine, etc.)
3. For Apokyn®
a. Documented trial and failure (of at least 12 weeks), intolerance or contraindication to Kynmobi®

QUANTITY LIMITS:
Kynmobi®: Five (5) films/day

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist.

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A

ARANESP/RETACRIT/EPOGEN/PROCRIT

MEDICATION(S)
ARANESP, EPOGEN, PROCRIT, RETACRIT 10,000 UNIT/ML VIAL, RETACRIT 2,000 UNIT/ML VIAL, RETACRIT 3,000 UNIT/ML VIAL, RETACRIT 4,000 UNIT/ML VIAL, RETACRIT 40,000 UNIT/ML VIAL

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with uncontrolled hypertension
Anemia induced from hepatitis C therapy

REQUIRED MEDICAL INFORMATION
Hemoglobin and Hematocrit levels within 30 days prior to initiation of therapy.

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be for one (1) year

OTHER CRITERIA
1. All diagnoses with the exception of 2e (preoperative use in patients scheduled for elective non-cardiac, nonvascular surgery), must have documented Hemoglobin (HGB) levels of less than or equal to 10g/dl within the 30 days prior to initiation of therapy
AND
2. Must meet all of the listed criteria below for each specific diagnosis:
a. Treatment of Anemia in Chronic Kidney Disease (CKD)
i. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%
b. Treatment of anemia in patients with cancer:
i. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level 100 mcg/L or

serum transferrin saturation 20%
AND
ii. One of the following clinical scenarios:
1. Patient has comorbid chronic kidney disease
2. Patient undergoing palliative treatment
3. Patient is currently on myelosuppressive chemotherapy and anemia is not able to be managed by transfusion therapy
c. Treatment of Anemia in Myelodysplastic Syndromes (MDS) or with myelofibrosis
i. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level 100 mcg/L or serum transferrin saturation 20%
ii. Must have documented current (within last 3 months) endogenous serum erythropoietin levels less than or equal to 500 mU/mL
d. Anemia associated with zidovudine-treated HIV-infection patients
i. Documented current (within last 3 months) endogenous serum erythropoietin level is less than or equal to 500 mU/ml
ii. Zidovudine dose is less than or equal to 4200 mg/week
e. Preoperative use in patients scheduled for elective noncardiac and nonvascular surgery, all of the following criteria must be met:
i. Member has preoperative HGB between 10 and 13 g/dL
ii. The surgery has a high-risk for perioperative blood loss (e.g., expected to lose more than 2 units of blood)
iii. Patient is unwilling to donate autologous blood pre-operatively

Reauthorization:
1. Documentation of continued medical necessity (e.g., ongoing chronic kidney disease)
2. Documented HGB levels of less than or equal to 12 g/dl within previous 30 days

BENLYSTA

MEDICATION(S)
BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE

COVERED USES
N/A

EXCLUSION CRITERIA
Belimumab will not be approved if any of the following are present:
1. Severe active lupus nephritis (presence of proteinuria of greater than or equal to 3.5 gm/day)
2. Severe active central nervous system lupus
3. Current use of other biologic immunomodulator
4. Current use of intravenous (IV) cyclophosphamid

REQUIRED MEDICAL INFORMATION
• ANA, anti-dsDNA antibody, or anti-Sm antibody
• For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary
• For IV infusion only: patient’s weight

AGE RESTRICTION
Age 5 years and older for IV infusion
Age 18 years and older for subcutaneous injection

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a Rheumatologist

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months

OTHER CRITERIA
All of the following must be met:
1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) by a rheumatologist
AND
2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one (1) of the following:
a. Positive Antinuclear antibody (ANA)

b. Positive anti-double-stranded DNA (anti-dsDNA) on two (2) or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range
c. Positive anti-Smith (Anti-Sm)
d. Positive anti-Ro/SSA and anti-La/SSB antibodies
AND
3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one (1) of the following:
a. Oral corticosteroid(s)
b. Azathioprine
c. Methotrexate
d. Mycophenolate mofetil
e. Hydroxychloroquine
f. Chloroquine
g. Cyclophosphamide
4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, hydroxychloroquine, mycophenolate, azathioprine, methotrexate)

Reauthorization:
1. Documentation of positive clinical response to belimumab (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of belimumab)
2. Patient currently receiving standard therapy for SLE (excluding IV cyclophosphamide)

QUANTITY LIMIT:
• Belimumab 200 mg/mL single-dose prefilled autoinjector and glass syringe for subcutaneous injection: 4 mL per 28 days
• Belimumab powder for solution for IV use only (subject to audit): Initial dose of 10 mg/kg IV every 2 weeks for 3 doses and then continue every 4 weeks thereafter as maintenance
• Belimumab IV is available as:
o 120 mg in a 5-mL single-dose vial
o 400 mg in a 20-mL single-dose vial for injection
• Correct vial combination for each patient should be calculated to minimize waste (see Appendix 1)

BEPREVE/LASTACAFT/PAZEO

MEDICATION(S)
BEPREVE, LASTACAFT, PAZEO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Bepreve®, Lastacaft®, Pazeo®, and Zerviate®

1. Documented trial and failure, contraindication or intolerance to olopatadine 0.2% eye drops (generic for Pataday®)
AND
2. Documented trial and failure, contraindication or intolerance to azelastine ophthalmic solution (Optivar®).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
N/A

BPH TREATMENT- CIALIS, RAPAFLO

MEDICATION(S)
RAPAFLO, SILODOSIN

COVERED USES
N/A

EXCLUSION CRITERIA
Used for the treatment of erectile dysfunction, except for those groups with the benefit covering sexual dysfunctions or disorders (doses of up to 8 tablets per 30 days will be covered without restriction for these groups).

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed yearly to assess continued medical necessity and effectiveness of drug

OTHER CRITERIA
For Rapaflo®: Documentation of an adequate trial and failure*, or intolerance, to two formulary alpha-adrenergic blockers (e.g., tamsulosin, doxazosin, terazosin, alfuzosin).

For Medicaid Only:
For tadalafil (Cialis®) 5 mg daily for signs and symptoms of benign prostatic hyperplasia (BPH): Documentation of an adequate trial and failure*, intolerance, or contraindication to at least one formulary drug from EACH of the categories listed below:
1. Alpha-adrenergic blockers (e.g. tamsulosin, doxazosin, terazosin, alfuzosin)
AND
2. 5-alpha reductase inhibitor (e.g. finasteride or dutasteride)

*An adequate trial and failure is defined as daily use for at least 4 weeks of therapy without improvement in

signs and symptoms of BPH.

QUANTITY LIMIT:

Cialis® (tadalafil) 5 mg: 30 tablets per 30 days for BPH

CABLIVI

MEDICATION(S)
CABLIVI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an oncologist or hematologist

COVERAGE DURATION
Initial authorization will be approved for 30 days. Reauthorization will be approved up to a total duration of 58 days post-plasma-exchange.

OTHER CRITERIA
Initial Criteria:
1. Diagnosis of acquired thrombotic thrombocytopenic purpura
2. Documentation that therapy will be given in combination with plasma exchange therapy
3. Documentation that therapy will be given in combination with immunosuppressive therapy (i.e., glucocorticoids, rituximab)

Reauthorization criteria:
If the request is for a new treatment cycle:
1. Documentation of previous positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers)
2. Documentation that therapy will be given in combination with plasma exchange therapy and immunosuppressive therapy (i.e., glucocorticoids, rituximab)
3. Documentation that length of therapy post plasma exchange will not exceed 58 days

4. Documentation that patient has not had more than two recurrences of acquired thrombotic thrombocytopenic purpura while on therapy with caplacizumab. Recurrence is defined as initial platelet normalization followed by a reduction in platelet count that necessitates re-initiation of plasma exchange.

If request is for treatment extension:
1. Documentation of positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers)
2. Documentation that patient has signs of persistent underlying disease such as persistent severe ADAMTS13 deficiency
3. Documentation that length of therapy post plasma exchange will not exceed 58 days

QUANTITY LIMIT:

1 vial per day

CALCITONIN GENE-RELATED PEPTIDE RECEPTOR (CGRP) ANTAGONISTS FOR MIGRAINE PROPHYLAXIS

MEDICATION(S)

AIMOVIG AUTOINJECTOR, AIMOVIG AUTOINJECTOR (2 PACK), EMGALITY PEN, EMGALITY SYRINGE

COVERED USES

N/A

EXCLUSION CRITERIA

Concomitant use with another calcitonin gene-related (CGRP) agent

REQUIRED MEDICAL INFORMATION

Initial authorization for migraine prophylaxis (chronic and episodic):

1. Diagnosis of migraine headaches with at least four (4) headache days per month

AND

2. One of the following:

a. Trial and inadequate response to at least 6 weeks of at least one (1) prophylactic medication from one (1) of the following categories:

i. Anticonvulsants (i.e., divalproex, valproate, topiramate)

ii. Beta-blockers (i.e., metoprolol, propranolol, timolol)

iii. Antidepressants (i.e., amitriptyline, venlafaxine)

b. Documented intolerance or contraindication to an anticonvulsant, a beta blocker, AND an antidepressant listed above

AND

3. Documentation that if the patient is currently receiving botulinum toxin, treatment with botulinum toxin will be discontinued.

4. The patient has been evaluated for, and does not have, medication overuse headache

5. For non-preferred CGRP prophylactic agents (Ajovy®, Vyepti®): Trial and failure, intolerance, or contraindication to two of the preferred CGRP agents (Aimovig® and Emgality®)

Initial authorization for cluster headaches (Emgality® only):

1. Diagnosis of episodic cluster headaches with all of the following:

a. A history of at least five (5) cluster headache attacks with at least two of the cluster periods lasting at least 7 days

b. Cluster periods are separated by at least three (3) months of pain-free remission

AND

2. One of the following:

a. Trial and inadequate response to at least 6 weeks (while adherent to therapy) of at least one (1) of the following:
i. Verapamil
ii. Melatonin
iii. Lithium
iv. Topiramate
b. Documented intolerance or contraindication to all of the therapies listed above
AND
3. The patient has been evaluated for, and does not have, medication overuse headache

Reauthorization for all indications: Documented reduction in the severity or frequency of headaches

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For chronic (not episodic) migraine prophylaxis and cluster headaches: Must be prescribed by, or in consultation with, a headache specialist [e.g., neurologist, pain management specialist, or specialist with United Council for Neurologic Subspecialties (UCNS)]

COVERAGE DURATION
Initial authorization will be approved for 6 months.
Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
N/A

CAMBIA

MEDICATION(S)
CAMBIA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Diagnosis of migraine headache
AND
2. Trial and failure of or contraindication to sumatriptan
AND
3. Trial and failure of or contraindication to oral diclofenac potassium 50mg tablets.

QUANTITY LIMIT:

9 packets per 30 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for up to one year.

OTHER CRITERIA
N/A

CFTR MODULATORS - KALYDECO/ORKAMBI/SYMDEKO/TRIKAFTA

MEDICATION(S)
KALYDECO, ORKAMBI, SYMDEKO, TRIKAFTA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For ivacaftor (Kalydeco®):
Diagnosis of cystic fibrosis with documentation of at least one copy of a cystic fibrosis transmembrane regulator (CFTR) gene mutation that is responsive to ivacaftor (See Appendix 1 and/ or package insert)

For lumacaftor-ivacaftor (Orkambi®):
Diagnosis of cystic fibrosis with documentation of homozygous F508del mutation in the CFTR gene

For tezacaftor-ivacaftor (Symdeko™):
Diagnosis of cystic fibrosis with documentation of one (1) of the following:
1. Homozygous F508del mutation in the CFTR gene
OR
2. A copy of a mutation in the CFTR gene that is responsive to tezacaftor-ivacaftor based on clinical evidence and/or in vitro data (See Appendix 2 and/ or package insert), excluding F508del mutation

For elexacaftor- tezacaftor-ivacaftor (Trikafta™):
Diagnosis of cystic fibrosis with documentation of at least one F508del mutation in the CFTR gene

Reauthorization:
Documented response to therapy as defined as one (1) of the following:
a. A lack of decline in lung function as measured by the FEV1 when the patient is clinically stable
b. A reduction in the incidence of pulmonary exacerbations
c. Reduced respiratory symptoms (e.g., persistent productive cough, wheezing, shortness of breath)
d. A significant improvement in BMI by 10% from baseline

QUANTITY LIMIT:
Ivacaftor (Kalydeco®): 2 tablets/granule packets per day
Lumacaftor-ivacaftor (Orkambi®): 4 tablets per day

Tezacaftor-ivacaftor (Symdeko™): 2 tablets per day
elexacaftor- tezacaftor-ivacaftor (Trikafta™): 3 tablets per day

AGE RESTRICTION
For elexacaftor- tezacaftor-ivacaftor (Trikafta™): 12 years or older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a pulmonologist or provider at a Cystic Fibrosis Center.

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A

CHENODAL

MEDICATION(S)
CHENODAL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication is necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For use for gallstone dissolution, must be prescribed by a Gastroenterologist.

For use in cerebrotendinous xanthomatosis, must be prescribed by, or in consultation with, a Genetics or Metabolism Specialist.

COVERAGE DURATION
Initial authorization will be for six months. Reauthorization will be for one year.
Maximum total duration of therapy authorized for treatment of gallstones will be two (2) years.

OTHER CRITERIA
For use in gallstone dissolution:
1. Documentation that the patient is not a candidate for surgery
AND
2. Documentation of failure of an adequate trial of 6-month duration, contraindication, or intolerance to ursodiol

Reauthorization:
Documentation of positive clinical response to therapy

CHOLBAM

MEDICATION(S)
CHOLBAM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary. Patient weight. Dose and frequency requested. Baseline liver function tests (AST, ALT, GGT, ALP, total bilirubin, INR)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with medical geneticist, pediatric gastroenterologist, hepatologist, or other specialist experienced in treating inborn errors of metabolism.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for up to 1 year.

OTHER CRITERIA
For bile acid synthesis disorder: documentation of a single enzyme defect
For peroxisomal disorder including Zellweger spectrum disorders
1. Documentation of manifestations of at least one of the following:
a. Liver disease (eg, jaundice: elevated serum transaminases)
b. Steatorrhea
c. Complications from decreased fat-soluble vitamin absorption (eg, poor growth)
AND
2. The medication will be used as adjunctive therapy

Reauthorization:
Documentation of positive clinical response

CINRYZE / HAEGARDA / TAKHZYRO

MEDICATION(S)
HAEGARDA, TAKHZYRO

COVERED USES
N/A

EXCLUSION CRITERIA
Combination prophylaxis therapy with Cinryze®, Haegarda®, or Takhzyro®

REQUIRED MEDICAL INFORMATION
Complement Component C4 and C1-Esterase inhibitor OR C1-Esterase Functional.
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
Current patient weight

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an immunologist or an allergist.

COVERAGE DURATION
Initial prior authorization will be approved for 3 months. Reauthorization may be approved for one year.

OTHER CRITERIA
All of the following must be met:
1. Documentation of one of the following clinical criteria:
a. Self-limiting, noninflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours,
OR
b. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six hours,
OR
c. Recurrent laryngeal edema
AND
2. Documentation of greater than or equal to 2 HAE attacks per month on average for the past 3 months despite removal of triggers (eg. estrogen containing oral contraceptive, angiotensin converting enzyme

inhibitors) unless medically necessary
AND
3. Trial and failure, intolerance or contraindication to long-term prophylaxis with androgen therapy, such as danazol, stanozolol or oxandrolone unless not indicated (eg. pregnancy, lactation, pre-pubescent children),
AND
4. One of the following:
a. For HAE Type I and Type II, documentation of at least two (2) complement studies taken at least one month apart with the patient in their basal condition and after the first year of life that show:
i. C4 is less than 50 percent of the lower limit of normal
AND
ii. one of the following:
a. C1-inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal,
OR
b. C1-INH function is less than 50 percent of the lower limit of normal
b. For HAE with normal C1-INH or HAE Type III:
i. Confirmed Factor 12 (FXII) mutation
OR
ii. Positive family history for HAE AND attacks lack response with high dose antihistamines or corticosteroids.

For coverage of Cinryze®: Documentation of trial and failure or contraindication to Haegarda®.

REAUTHORIZATION:

Documentation must be provided showing benefit of therapy with reduction of frequency and severity of HAE attack episodes by greater than or equal to 50% from baseline.

QUANTITY LIMITS:

Cinryze®: 16 vials (500 units each vial) for 28 days
Haegarda®: Weight based 60 units/kg twice weekly for a 28-day supply (see appendix 2)
Takhzyro®: 2 vials (300 mg each vial) per 28-day supply

Dosing regimens beyond quantity limits will only be approved if evidence-based-rationale is provided.

CONSTIPATION AGENTS

MEDICATION(S)
AMITIZA, MOTEGRITY, MOVANTIK, SYMPROIC

COVERED USES
N/A

EXCLUSION CRITERIA
Current, or history of, bowel obstruction

REQUIRED MEDICAL INFORMATION
1) For all requests, the patient must have an FDA labeled indication for the requested agent.
2) For patients already established on the requested product (starting on samples will not be considered as established on therapy):
a) Documentation of response to therapy (e.g., less straining, less pain on defecation, improved stool consistency, increased number of stools per week or reduction in the number of days between stools)
3) For patients not established on the requested product must meet ALL of the following indication-specific criteria:
a) For chronic idiopathic constipation (CIC):
i) Documentation of weekly constipation (less than 3 spontaneous bowel movements) for at last 3 months
ii) Screen for constipation-inducing medications and medical rationale provided for continuing these medications, if applicable
iii) Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of ALL of the following:
(1) Regular use of dietary fiber supplementation (e.g. cereal, citrus, fruits or legumes) or use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids),
(2) A stimulant laxative (e.g. senna, bisacodyl)
(3) Routine laxative therapy, with a different mechanism of action than the laxative(s) listed above (e.g., lactulose, Miralax®)
b) For irritable bowel syndrome with constipation (IBS-C):
i) Documentation of recurrent abdominal pain occurring, on average, at least 1 day per week during the previous 3 months with two (2) or more of the following criteria:
(1) Related to defecation (either increased or improved pain)
(2) Associated with a change in stool frequency
(3) Associated with a change in stool form (appearance)
ii) Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of ALL of the following:
(1) Regular use of dietary fiber supplementation (e.g. cereal, citrus, fruits or legumes) or use of bulking

agents (e.g., psyllium or methylcellulose taken with adequate fluids)
(2) Routine laxative therapy with polyethylene glycol (Miralax®)
iii) For Amitiza®: patient is a woman aged 18 years or older
iv) For Zelnorm®: patient is a woman aged 65 years or younger without contraindication to therapy. Contraindications include:
(1) History of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina
(2) History of ischemic colitis or other forms of intestinal ischemia, bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi dysfunction, or abdominal adhesion
(3) Moderate or severe hepatic impairment
(4) Severe renal disease or end-stage renal disease
c) **For opioid-induced constipation (OIC) (Amitiza®, Movantik®, and Symproic® only):
i) Documentation of less than 3 spontaneous bowel movements per week
ii) Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of ALL of the following:
(1) A stimulant laxative (e.g. senna, bisacodyl)
(2) Routine laxative therapy, with a different mechanism of action than the laxative above (e.g. lactulose, Miralax®)

**For Medicaid, please note that chronic constipation secondary to continuous opioid use as part of a palliative care regimen, or for treatment of active cancer pain, is approvable without meeting criterion c.ii. only if medical rationale is sufficient

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For OIC: Initial authorization will be approved for 6 months. Reauthorization will be approved for one year
For CIC or IBS: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A

CORLANOR

MEDICATION(S)
CORLANOR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a cardiologist or electrophysiologist.

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
For chronic heart failure, all of the following must be met:
1. Symptoms consistent with New York Heart Association (NYHA) Class II, III, or IV
2. Left-ventricular ejection fraction of 35% or less
3. Documentation that patient is currently in normal sinus rhythm with resting heart rate of at least 70 bpm
4. On a maximally tolerated dose of a beta-blocker (i.e., carvedilol, metoprolol succinate, bisoprolol) or contraindication to their use
5. Documented trial and failure, contraindication, or intolerance to maximally tolerated dose of an ACE inhibitor (e.g., lisinopril, enalapril) or ARB (e.g., losartan, valsartan)
6. Documentation that the patient has been hospitalized for worsening heart failure in the previous 12 months

For inappropriate sinus tachycardia (IST):
1. Documentation of a sinus heart rate of greater than100 bpm at rest (with a mean 24-hour heart rate

greater than 90 bpm)
2. Documentation that other causes of sinus tachycardia have been ruled out (such as thyroid disease, medications or drugs)
3. Documentation that inappropriate sinus tachycardia is causing significant functional impairment or distress

DALIRESP

MEDICATION(S)
DALIRESP

COVERED USES
N/A

EXCLUSION CRITERIA
• Moderate to severe hepatic impairment (Child Pugh B or C)

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met:
1. A confirmed diagnosis of severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis and a history of exacerbations
AND
2. An adequate trial and failure, contraindication or intolerance to maintenance treatment with triple therapy including a long-acting beta2 agonist (LABA), long-acting antimuscarinic agonist (LAMA), and an inhaled corticosteroid (ICS)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a pulmonologist

COVERAGE DURATION
Initial authorization and reauthorization for 12 months.

OTHER CRITERIA
N/A

DENAVIR/SITAVIG/XERESE/ZOVIRAX

MEDICATION(S)
ACYCLOVIR 5% OINTMENT, DENAVIR, ZOVIRAX 5% OINTMENT

COVERED USES
N/A

EXCLUSION CRITERIA
• Genital or mucocutaneuos herpes simplex
• Suppressive therapy (greater than 10 days course)
• Retreatment with acyclovir buccal tablets (Sitavig®) for the same episode of cold sore infection

REQUIRED MEDICAL INFORMATION
For herpes labialis (cold sores):
1. Documented trial and failure*, intolerance or contraindication to a generic oral antiviral medication (See Appendix 1 for recommended dosing)
2. For acyclovir buccal tablets (Sitavig®), acyclovir cream (Zovirax® cream), acyclovir/hydrocortisone cream (Xerese®), or penciclovir cream (Denavir®): Documented trial and failure*, contraindication or intolerance to acyclovir ointment

*Trial and failure is defined as no improvement in lesions 10 days after starting treatment.

QUANTITY LIMIT:
Acyclovir buccal tablets (Sitavig®) is limited to one 50mg tablet per 30 days.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A

DIACOMIT

MEDICATION(S)
DIACOMIT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met:
1. Documentation of seizures associated with Dravet Syndrome (DS)
2. Documentation of inadequate control on clobazam or valproate (unless contraindicated), despite optimized therapy
3. Documentation that stiripentol will be used in combination with clobazam
4. Dose will not exceed 50mg/kg (up to maximum 3,000mg) per day
For reauthorization or if patient is currently established on therapy (Note: starting on samples will not be considered established on therapy) all of the following criteria must be met:
1. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy
2. Dose will not exceed 50mg/kg (up to maximum 3,000mg) per day
QUANTITY LIMIT:
250mg: 360 packets or capsules per 30 days
500mg: 180 packets or capsules per 30 days

AGE RESTRICTION
Approved for 2 years of age and older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an epilepsy specialist

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
N/A

DIHYDROERGOTAMINE

MEDICATION(S)
D.H.E.45, DIHYDROERGOTAMINE 1 MG/ML AMP, DIHYDROERGOTAMINE 4 MG/ML SPRY, MIGRANAL

COVERED USES
N/A

EXCLUSION CRITERIA
• Use during pregnancy
• History of ischemic heart disease
• Hemiplegic or basilar migraine

REQUIRED MEDICAL INFORMATION
1. Documented trial, failure, intolerance or contraindication to, at least two formulary, generic triptan medications (e.g. sumatriptan, rizatriptan)
2. Documented trial, failure, intolerance, or contraindication to ergotamine/caffeine tablets (Cafergot®). If unable to use oral formulations, then a documented trial, failure, intolerance or contraindication ergotamine/caffeine rectal suppositories (Migergot®) will be required.

QUANTITY LIMIT:
Dihydroergotamine nasal spray: 8 units per 30 days
• Each unit consists of one vial and one nasal spray applicator. Each vial contains 4 mg dihydroergotamine in 3.5 mL.
• Each vial must be discarded 8 hours after preparation
• Dosing: 0.5 mg (one spray) every 15 minutes to maximum dose of 3 mg per 24 hours or 4 mg per 7 days
Dihydroergotamine injection: 24 mL per 28 days
• Each vial contains 1 mg dihydroergotamine in 1 mL
• Dosing: 1 mL every hour to maximum dose of 3 mL per 24 hours or 6 mL per 7 days

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA

N/A

DOPTELET, MULPLETA

MEDICATION(S)
DOPTELET, MULPLETA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Recent platelet counts
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for 18 years of age and older.

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an oncologist, hematologist, gastroenterologists or liver specialist.

COVERAGE DURATION
For Treatment of Thrombocytopenia in Patients with Chronic Liver Disease (CLD): Authorization will be approved for 1 month for 1 course of treatment (15 tablets of Doptelet® or 7 tablets of Mulpleta®)

Treatment of Thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP) (Doptelet only): Initial authorization for 3 months and reauthorization for 1 year

OTHER CRITERIA
For Treatment of Thrombocytopenia in Patients with Chronic Liver Disease (CLD):
For Doptelet®:
Must meet all of the following:
1. Diagnosis of chronic liver disease
2. Platelet count of less than 50,000 /µL (50 x 109 /L)
3. Documentation that patient will have a scheduled medical or dental procedure within the next 30 days and therapy will be started 10-13 days prior to the procedure

For Mulpleta®: Must meet all of the following:
1. Diagnosis of chronic liver disease
2. Platelet count of less than 50,000 /µL (50 x 109 /L)
3. Documentation that patient will have a scheduled medical or dental procedure within the next 30 days and therapy will be started 8-14 days prior to the procedure
4. Documented trial, failure, intolerance or contraindication to avatrombopag (Doptelet®)

Treatment of Thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP) (Doptelet® only)

Initial authorization:
1. Diagnosis of chronic immune thrombocytopenia (ITP)
2. Platelet count of less than 30,000/uL (30 x 109 /L)
3. Inadequate response to at least TWO of the following therapies:
a. Corticosteroids
b. Immunoglobulins
c. Splenectomy
d. Rituximab

Reauthorization:
1. Documentation of an improvement in platelet count to at least 50,000 /uL (50 x 109 /L) or greater

QUANTITY LIMIT:

For Mulpleta®: 7 tablets per month

DPP4 INHIBITORS

MEDICATION(S)
ALOGLIPTIN, ALOGLIPTIN-METFORMIN, ALOGLIPTIN-PIOGLITAZONE, GLYXAMBI, JANUMET, JANUMET XR, JANUVIA, JENTADUETO, JENTADUETO XR, KAZANO, KOMBIGLYZE XR, NESINA, ONGLYZA, OSENI, TRADJENTA

COVERED USES
N/A

EXCLUSION CRITERIA
Type 1 diabetes

REQUIRED MEDICAL INFORMATION
For initial authorization, ALL the following criteria are required:
1. Documentation of trial and failure*, contraindication or intolerance to metformin therapy, at the maximum effective dose of 2000 mg/day
AND
2. Documented trial and failure* to one (1) of the following medication classes, or intolerance/contraindication to all classes listed below:
a. Sulfonylurea (e.g., glimepiride)
b. Thiazolidinedione (e.g., pioglitazone)
c. Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., empagliflozin (Jardiance®)]
d. Glucagon-like peptide-1 (GLP-1) receptor agonist (e.g., liraglutide, exenatide, semaglutide)
AND
3. A documented HbA1c, obtained within the last six months that is greater than or equal to 7% and less than or equal to 10%.

*Trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy

For Reauthorization:
Documentation of HbA1c less than or equal to 9% that was checked within the last 6 months

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA

N/A

DRONABINOL

MEDICATION(S)
DRONABINOL, MARINOL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Nausea/vomiting with chemotherapy: Initial authorization and reauthorization will be approved for six months.
AIDS wasting: Initial authorization and reauthorization will be approved for three months.

OTHER CRITERIA
For nausea and vomiting associated with cancer chemotherapy:
1. Patient must meet the following criteria:
a. Documentation of trial and failure, contraindication or intolerance to a 5HT-3 receptor antagonist (e.g., ondansetron). AND
b. Documentation of trial and failure, contraindication or intolerance to one of the following formulary medications unless contraindicated: promethazine, prochlorperazine, chlorpromazine, or metoclopramide.
For anorexia with weight loss in patients with AIDS:
1. Documentation that patient is currently taking anti-retroviral therapy
2. If patient is less than 65 years of age: Documentation of trial and failure, contraindication, or intolerance to megestrol (Megace®)

DUPIXENT

MEDICATION(S)
DUPIXENT PEN, DUPIXENT SYRINGE

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with another therapeutic immunomodulator agent utilized for the same indication

REQUIRED MEDICAL INFORMATION
For initial authorization, must meet all of the following criteria:

For moderate-severe atopic dermatitis:
1. Diagnosis of moderate to severe atopic dermatitis despite use of therapies outlined in criterion number 2 below, as defined by all of the following:
a. Patient has a minimum body surface area (BSA) involvement of at least 10% (or hand, foot or mucous membrane involvement)
b. Patient has severe symptoms such as erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification
c. Chronic condition, affecting patient for more than one (1) year
d. For Medicaid (OHP) only: Documentation that patient is having functional impairment due to atopic dermatitis (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction)

2. Documented trial and failure of an adequate treatment course with at least one agent from all each of the following treatment modalities:
a. Moderate to high potency topical corticosteroids (e.g., clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least two (2) weeks
b. Topical calcineurin inhibitor (e.g., tacrolimus ointment) applied twice daily for at least one (1) month
c. For Medicaid only: Systemic immunomodulatory agents (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate or oral corticosteroids) for at least two (2) months unless contraindicated

Reauthorization requires documentation of reduction from baseline of flares, pruritus, and affected BSA

For eosinophilic asthma:
1. Documentation of eosinophilic asthma by one of the following:
a. A blood eosinophil count greater than 150 cells/microliter in the past 12 months

b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids
2. Documentation of treatment with maximally tolerated dose of medium to high –dose inhaled corticosteroid plus a long-acting inhaled beta2-agonist and has been compliant to therapy in the past 3 months (this may be verified by pharmacy claims information)
3. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following:
a. Asthma Control Test (ACT) score less than20 or Asthma Control Questionnaire (ACQ) score greater than 1.5
b. At least 2 asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
c. At least 1 asthma exacerbation requiring hospitalization, emergency room or urgent care visit

Reauthorization requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

For corticosteroid dependent asthma:
1. Documentation of corticosteroid dependent asthma defined as consistent treatment with oral corticosteroids for the past six months (5 mg to 35 mg of prednisone/prednisolone (or equivalent)). (This may be verified by pharmacy claims information).
2. Documentation that in the past 3 months patient is adherent to a combination of a high-dose inhaled corticosteroid and a long-acting inhaled beta2-agonist. (This may be verified by pharmacy claims information)
3. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following:
a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than 1.5
b. Documentation, within the last 12 months, of one or more asthma exacerbations defined as any of the following:
i. Increase in dose of systemic corticosteroid treatment
ii. Urgent care visit or hospital admission
iii. Intubation

Reauthorization requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

Adjunct Therapy for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), all of the following must be met:
1. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan
2. Documentation of one (1) of the following:
a. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery
b. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids

3. Patient has tried and had an inadequate response to a 3-month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids
4. Documentation that patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with dupilumab

Reauthorization for CRSwNP: Documentation of positive clinical response to therapy such as symptom improvement

QUANTITY LIMIT:
Two (2) 200 mg injections per 28 days
Two (2) 300 mg injections per 28 days.
Note:
• The recommended dose of Dupixent® for adults with atopic dermatitis is an initial loading dose of 600 mg (two 300 mg injections) subcutaneously, followed by 300 mg given every other week for maintenance.
• The recommended dose of Dupixent® for adolescents (12 year of age and older) for eosinophilic and oral corticosteroid dependent asthma is an initial loading dose of 400 mg (two 200 mg injections) or 600 mg (two 300 mg injections) subcutaneously, followed by 200 mg or 300 mg given every other week for maintenance
• The recommended dose of Dupixent® for adults with CRSwNP is 300 mg every other week

AGE RESTRICTION
• Moderate-to-severe atopic dermatitis: Age 6 years and older
• Eosinophilic and corticosteroid dependent asthma: Age 12 years and older
• Chronic rhinosinusitis with nasal polyposis: Age 18 years and older

PRESCRIBER RESTRICTION
• Moderate-to-severe atopic dermatitis: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist
• Eosinophilic and corticosteroid dependent asthma: Must be prescribed by, or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)
• Chronic rhinosinusitis with nasal polyposis: otolaryngologist, allergist, pulmonologist

COVERAGE DURATION
For atopic dermatitis and chronic rhinosinusitis with nasal polyposis: Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.
For asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A

EGRIFTA

MEDICATION(S)
EGRIFTA, EGRIFTA SV

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Waist circumference

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 6 months.

OTHER CRITERIA
1. Patient must be at least 18 years old and have a diagnosis of HIV-associated lipodystrophy
AND
2. Documentation of patient’s waist circumference
a. Waist circumference greater than or equal to 37.4 inches (95 cm) for males
b. Waist circumference greater than or equal to 37 inches (94 cm) for females
AND
3. Documentation of waist-to-hip ratio
a. Waist-to-hip ratio greater than or equal to 0.94 for males
b. Waist-to-hip ratio greater than or equal to 0.88 for females
AND
4. Documentation of a body mass index (BMI) greater than 20 kg/m2
AND

5. Documentation of fasting blood glucose (FBG) of less than or equal to 150 mg/dL (8.33 mmol/L)
AND
6. Documentation that patient has been on a stable regimen of antiretrovirals for at least 8 weeks

Reauthorization will require documentation of clinial improvement (e.g., decrease in waist circumference, improvement in visceral adipose tissue).

ENSTILAR/TACLONEX/TACLONEX SCALP

MEDICATION(S)
CALCIPOTRIENE-BETAMETHASONE, CALCIPOTRIENE-BETAMETHASONE DP, TACLONEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
12 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
For treatment of psoriasis on the scalp, documentation of trial, failure, contraindication or intolerance to both of the following:
1. Corticosteroid treatment for the scalp (e.g., clobetasol shampoo, fluocinolone scalp oil/solution)
2. Calcipotriene solution

For treatment of psoriasis of the body:
1. Documentation of trial, failure, contraindication or intolerance to at least one high-potency corticosteroid treatment (e.g., clobetasol, betamethasone)
2. Documentation of trial, failure, contraindication or intolerance to at least one of the following:
a. Calcipotriene cream/solution
b. Tazarotene cream or gel
c. Calcitriol ointment

EPIDIOLEX

MEDICATION(S)
EPIDIOLEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization:
1. Documentation that patient has one of the following:
a. Seizures associated with Lennox-Gastaut syndrome (LGS)
b. Seizures associated with Dravet syndrome (DS)
c. Tuberous sclerosis complex (TSC)
2. Documented trial, failure, intolerance or contraindication to two* of the following: (*Coverage for Medicaid requires only one of the following)
a. Valproate / Valproic acid
b. Lamotrigine
c. Clobazam
d. Levetiracetam
e. Topiramate
f. Felbamate
g. Zonisamide
h. Vigabatrin
3. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs
4. Baseline liver function tests must be documented
5. Dose will not exceed:
a. 20 mg/kg/day in Lennox-Gastaut syndrome or Dravet Syndrome
b. 25mg/kg/day in tuberous sclerosis complex

Reauthorization:

1. Documentation of recent liver function test
2. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy
3. Dose continues to not exceed 20 mg/kg/day in Lennox-Gastaut syndrome or Dravet Syndrome or

25mg/kg/day in tuberous sclerosis complex

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescriber by or in consultation with an epilepsy specialist or pediatric neurologist

COVERAGE DURATION

Initial authorization will be approved for 6 months and reauthorization will be approved for 1 year

OTHER CRITERIA

N/A

ESBRIET/OFEV

MEDICATION(S)
ESBRIET, OFEV

COVERED USES
N/A

EXCLUSION CRITERIA
Combination therapy with pirfenidone (Esbriet®) or nintedanib (Ofev®)

REQUIRED MEDICAL INFORMATION
Initial Authorization:
For Idiopathic Pulmonary Fibrosis (IPF)
1. Diagnosis of Idiopathic Pulmonary Fibrosis
a. Note: Confirmed by exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, drug toxicity, or connective tissue disease
AND
2. Presence of a histological pattern associated with usual interstitial pneumonia (UIP) on high-resolution computed tomography (HRCT) with or without confirmation of UIP by surgical lung biopsy

For Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (Ofev® only):
1. Confirmed diagnosis of systemic sclerosis
AND
2. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT tomography

For other chronic fibrosing interstitial lung diseases with a progressive phenotype (Ofev® only):
1. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT tomography
AND
2. One (1) of the following criteria:
a. Relative decline in FVC of at least 10% of predicted value (as reported by spirometry performed on two different dates within the last two years)
b. Relative decline in FVC of at least 5% of predicted value combined with worsening of respiratory symptoms
c. Relative decline in FVC of at least 5% of predicted value combined with increased extent of fibrotic changes on chest imaging
d. Increased extent of fibrotic changes on chest imaging combined with worsening of respiratory symptoms
e. Increased fibrotic changes on HRCT

Reauthorization:

Documentation of positive clinical response to pirfenidone (Esbriet®) or nintedanib (Ofev®), such as slowed rate or lack of declining lung function (e.g., FVC, DLCO) and improved or stable respiratory symptoms (e.g., cough, dypnea).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For all indications: Must be prescribed by or in consultation with a pulmonologist
For SSc-ILD only: Must be prescribed by or in consultation with a pulmonologist or rheumatologist

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A

EUCRISA

MEDICATION(S)
EUCRISA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Documentation of trial and failure of an adequate treatment course (2 weeks or longer) of two (2) topical corticosteroids, including one (1) high potency corticosteroid (such as betamethasone dipropionate augmented ointment, clobetasol propionate cream or ointment, or halobetasol cream/ointment), unless member has a contraindication (such as an affected area that is not amenable to topical corticosteroid)
AND
2. Documentation of trial, failure, intolerance or contraindication to topical tacrolimus

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A

EXTAVIA

MEDICATION(S)
EXTAVIA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of trial and failure, contraindication, or intolerance to two of the following OR medical rationale why therapies cannot be tried:
a. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®)
b. Interferon-beta 1b (Betaseron®)
c. Dimethyl fumarate (Tecfidera®)
d. Glatiramer acetate (Copaxone®)
e. Teriflunomide (Aubagio®)
f. Fingolimod (Gilenya®)
g. Diroximel fumarate (Vumerity®)
h. Ozanimod hydrochloride (Zeposia®)
i. Siponimod (Mayzent®)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a Neurologist.

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
N/A

FENTANYL CITRATE

MEDICATION(S)

ACTIQ, FENTANYL CIT OTFC 1,200 MCG, FENTANYL CIT OTFC 1,600 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 400 MCG, FENTANYL CITRATE OTFC 600 MCG, FENTANYL CITRATE OTFC 800 MCG

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation of all the following:
1. Treatment of breakthrough cancer pain (prescriber MUST submit chart notes or other documentation supporting a diagnosis of cancer related pain AND list type of cancer)
AND
2. Failure of or intolerance to other oral or parenteral short-acting narcotic formulary agents used for breakthrough pain
AND
3. Pain is not controlled with long-acting narcotic analgesics
AND
4. For Abstral®, Fentora®, Lazanda® and Subsys®:
a. Documented trial and failure, contraindication, or intolerance to generic fentanyl citrate lozenge/troche

Reauthorization:

1. Documentation that patient continues to have breakthrough cancer pain (prescriber MUST submit recent chart notes or other documentation supporting a diagnosis of cancer related pain AND list type of cancer)
AND
2. Documentation of successful response to the medication

QUANTITY LIMIT:

120 lozenge/troche per 30 days
Fentora® and Abstral®: Limited to 120 tablets per 30 days
Lazanda®: Limited to 30 bottles per 60 days. (Each bottle contains 8 sprays)
Subsys®: Limited to 120 units (sprays) per 30 days

AGE RESTRICTION

Fentanyl citrate lozenge/troche: Approved for 16 years or older

Abstral®, Fentora®, Lazanda®, Subsys®: Approved for 18 years or older

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an oncologist or pain specialist

COVERAGE DURATION

Initial authorization for six months. Reauthorization for one year

OTHER CRITERIA

N/A

FORTEO

MEDICATION(S)
FORTEO, TERIPARATIDE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
BMD T-score, FRAX.
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an endocrinologist or rheumatologist

COVERAGE DURATION
May be approved for up to 2 years, ensuring the cumulative duration of osteoanabolic therapy does not exceed 2 years in a lifetime. Duration of osteoanabolic therapy is defined as cumulative duration spent on any of the three therapies: abaloparatide. teriparatide, or romosozumab.

OTHER CRITERIA
For the treatment or prevention of osteoporosis
1. Must meet ONE of the following criteria:
a. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures
b. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 and high risk for fracture, defined as one of the following:
i. Age more than 80 years
ii. Chronic glucocorticoid use
iii. Documented increased fall risk
c. Patient has a spine or hip BMD T-score less than or equal to -2.5 and one of the following:
i. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy

ii. Documented contraindication or intolerance to therapy with all of the following: 1. denosumab, 2. oral bisphosphonate (e.g., alendronate), and 3. IV bisphosphonate therapy (i.e., zoledronic acid)
d. Patient has a spine or hip BMD T-score between -1.0 and -2.5 and BOTH of the following:
i. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%
ii. One of the following:
1. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
2. Documented contraindication or intolerance to therapy with all of the following:
a. Denosumab
b. Oral bisphosphonate (e.g., alendronate)
c. IV bisphosphonate therapy (i.e., zoledronic acid)
2. For female patients only:
a. Documentation of trial and failure to Tymlos® (abaloparatide). Failure is defined as a new fracture or worsening bone mineral density while adherent to Tymlos® (abaloparatide).
AND
b. Total duration of treatment with Tymlos® (abaloparatide) has not exceeded two years.

GALAFOLD

MEDICATION(S)
GALAFOLD

COVERED USES
N/A

EXCLUSION CRITERIA
• Given concurrently with Enzyme Replacement Therapy [agalsidase beta (Fabrazyme®)]
• Severe renal impairment or end-stage renal disease

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for 18 years and older.

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a metabolic specialist, geneticist or prescriber with experience treating lysosomal storage disorders.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 1 year.

OTHER CRITERIA
1. Diagnosis of Fabry Disease
2. Documentation that patient has an amenable galactosidase alpha gene (GLA) variant based on an in vitro assay

QUANTITY LIMIT:

Galafold® 123 mg capsule: 14 capsules per 28 days (0.5 capsules per day) *
*Note Galafold® is dosed every other day

GAMMA GLOBULIN (IGG)

MEDICATION(S)
CUTAQUIG, GAMMAKED, GAMUNEX-C, HIZENTRA, HYQVIA, XEMBIFY

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient weight, dose, frequency and duration

IgA, IgM, IgG, T4 cell count, anti-GM1, platelet counts may be required (See indication specific criteria)

For initiation, a prior authorization form and documentation of medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an appropriate specialist (i.e. a Neurologist for Multiple Sclerosis or an immunologist, hematologist or infections disease expert for Primary Immunodeficiency)

COVERAGE DURATION
Generally, initial authorization is up to 6 months subject to criteria and reauthorization is up to 1-year subject to criteria. See Table 2 for indication specific coverage duration

OTHER CRITERIA
Initial Authorization for ALL indications:
1. The medical diagnosis a FDA approved indication or is listed as a covered medical condition below and any indication specific criteria in the policy is met
AND
2. Requested dosage, frequency and length of therapy are supported by FDA-approved labeling, accepted compendia and/ or evidence-based practice guidelines (See Table 1). If request is for a non-standard dose, frequency or length, medical rational should be provided and exceptions will be considered on a case by cases basis. Dosing is subject to audit.

Re-Authorization for ALL indications:

1. Documentation of response to therapy and any indication specific re-authorization criteria listed below is met

Indication-Specific Requirements:

Primary immune deficiency disorders such as agammaglobulinemia, hypogammaglobulinemia (i.e., common variable immunodeficiency), Hyper-IgM (i.e., X-linked or autosomal recessive hypogammaglobulinemia), Wiskott-Aldrich syndrome or Secondary immunodeficiency due to drugs/biologics agents, underlying disease or other causes:
1. Documentation of significant recurrent infections
AND
2. One of the following
a. Laboratory evidence of immunoglobulin deficiency:
i. Agammaglobulinemia (total pre-treatment IgG less than 200 mg/dL)
ii. Persistent hypogammaglobulinemia (total IgG less than 400 mg/dl, or at least two standard deviations below normal, on at least two occasions)
OR
b. Deficiency in producing antibodies in response to vaccination

Reauthorization:

1. Documentation that treatment has been effective in reducing the number or severity of clinical infections

Prevention of infections in patients with B-cell chronic lymphocytic leukemia (CLL):
1. Documented pre-treatment endogenous IgG less than 500 mg/dL
AND
2. History of recurrent, severe bacterial infections (e.g., pneumonia, sinusitis, otitis media)

Kawasaki Disease:
1. Documentation that use is for acute treatment given in conjunction with aspirin and within ten days of the onset of symptoms

Idiopathic or Immune Thrombocytopenic Purpura (ITP):
(Platelet counts expressed per mm3 and should be obtained within the past 30 days)

For children with ITP:
1. Documentation of one of the following:

a. Platelet count less than 20,000 and significant mucous membrane bleeding
b. Platelet count less than 10,000 and minor purpura
c. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss

Pregnant Women with ITP:
1. Documentation of one of the following:
a. Platelet count is less than100,000
b. Past history of splenectomy
c. Past history of delivered infant with autoimmune thrombocytopenia

Adult Patients with ITP:
1. Documentation of one of the following:
a. Platelet count of less than 30,000
b. Platelet count less than 50,000 with acute bleeding or high-risk of bleeding
c. To defer or avoid splenectomy
d. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss (platelet count goal is generally greater than 50,000)
2. Documentation that IGG product will be used in combination with corticosteroid therapy or corticosteroid therapy is contraindicated

Dermatomyositis and polymyositis:
1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (i.e. prednisone or methylprednisolone)
AND
2. Documented trial, failure, intolerance or contraindication to immunosuppressant therapy (e.g., methotrexate, azathioprine, cyclosporine, 6-mercaptopurine, chlorambucil, cyclophosphamide)
AND
3. Documentation of severe symptoms/disability despite previous therapy with above agents

Reauthorization:

Documented response to therapy

Chronic inflammatory demyelinating polyneuropathy (CIDP):
1. Documentation of severe disability
AND
2. One of the following:
a. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (i.e. prednisone or methylprednisolone)

b. Documentation of pure motor CIDP

Autoimmune Hemolytic Anemia:
1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (i.e. prednisone or methylprednisolone)
AND
2. Documented trial, failure, intolerance or contraindication to another conventional therapy for autoimmune hemolytic anemia (e.g., splenectomy, cyclophosphamide, azathioprine, cyclosporine)

Guillain-Barre Syndrome:
1. Documentation that symptom onset is within 2 weeks or symptoms are severe (e.g. unable to ambulate independently)
AND
2. Documented trial, failure, intolerance or contraindication to plasma exchange

Multifocal motor neuropathy:
1. Confirmed diagnosis: motor involvement of at least two nerves (for more than one month) without symptoms of sensory abnormalities
AND
2. Documentation of severe disease/disability

Multiple Sclerosis:
1. Documentation of relapsing/remitting disease
AND
2. Documented trial, failure, intolerance or contraindication to at least two conventional therapies (e.g., glatiramer, interferon beta, dimethyl fumarate)

Myasthenia Gravis:

Myasthenic exacerbation:
1. Evidence of myasthenic exacerbation, defined by at least one of the following symptoms in the last month:
a. Difficulty swallowing
b. Acute respiratory failure
c. Major functional disability responsible for the discontinuation of physical activity

Refractory disease:
1. Documentation that patient has severely impaired function due to myasthenia gravis
AND
2. Documented trial, failure, intolerance or contraindication to at least two of the following conventional

therapies:
a. Acetylcholinesterase inhibitors (e.g., pyridostigmine)
b. Corticosteroids (e.g., prednisone, methylprednisolone)
c. Immunosuppressive agents (e.g., azathioprine, cyclosporine, mycophenolate)
d. Plasma exchange

Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients:
1. Therapy is requested for use within 100 days after transplantation (documentation of transplantation date much be documented)
OR
2. Documentation of that member has hypogammaglobulinemia (see criteria for Secondary Hypogammaglobulinemia)

Autoimmune mucocutaneous blistering disease: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis
1. Documentation of biopsy proven disease
AND
2. Documented trial, failure, intolerance or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil).

GATTEX

MEDICATION(S)
GATTEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for 1 year and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a Gastroenterologist

COVERAGE DURATION
Initial authorization will be approved for 6 months, and reauthorization will be approved for 12 months.

OTHER CRITERIA
1. An initial nutritional assessment has been completed by a registered dietitian who has determined that oral/enteral nutrition is not sufficient to meet nutritional goals
2. Member is stable and dependent on parenteral support (fluids, electrolytes and/or nutrients) delivered at least three times per week
3. Teduglutide (Gattex®) has been made part of a treatment plan established by a Gastroenterologist or a hospital Metabolic Support Team:
a. Member evaluation indicates the possibility of success with treatment
b. Parameters have been defined to identify goals and measure improvement
Reauthorization:
Documentation that parenteral nutrition support requirement has decreased since initiation of teduglutide
QUANTITY LIMITS:
Round quantity to the nearest number of 5-mg kits, within 10% of calculated dose, based on weight-based dosing of 0.05 mg/kg once daily

GIVLAARI

MEDICATION(S)
GIVLAARI

COVERED USES
N/A

EXCLUSION CRITERIA
Use post liver transplant

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or hematologist

COVERAGE DURATION
Initial authorization will be approved for 6 months.
Reauthorization will be approved for 1 year.

OTHER CRITERIA
Initial authorization:
1. Documentation of diagnosis with acute hepatic porphyria (i.e, acute intermittent porphyria, hereditary corproporhyria, variegate porphyria, ALA dehydratase deficient porphyria)
AND
2. Active disease defined as two documented porphyria attacks within the past 6 months which required either hospitalization, urgent care visit, or intravenous hemin administration at home

Reauthorization criteria:

Documentation of reduction in the number or severity of porphyria attacks, reduction in number of hospitalizations due to acute porphyria attacks, or decreased hemin administration from baseline

GNRH ANTAGONISTS

MEDICATION(S)
ORILISSA

COVERED USES
N/A

EXCLUSION CRITERIA
• Patient has osteoporosis or severe hepatic impairment

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
May be covered for those patients at least 18 years old

PRESCRIBER RESTRICTION
Must be written by on in consultation with an obstetrician-gynecologist (OB-GYN)

COVERAGE DURATION
Orilissa® 150 mg once daily: Initial authorization for 6 months.
Reauthorization for up to 18 months. No reauthorization beyond 24 months

Orilissa® 200 mg twice daily: Initial authorization for 6 months.
No reauthorization.

OTHER CRITERIA
For endometriosis:
Initial Authorization
1. Documentation that patient has moderate to severe pain associated with endometriosis
2. Documentation that patient has trial and failure of, intolerance to, or contraindication to hormonal contraceptives

Reauthorization:
1. Request is for the 150 mg daily dose and total duration will not exceed 24 months
2. Documentation of a positive response to therapy (e.g., reduction in pain)

GONADOTROPIN RELEASING HORMONE AGONISTS

MEDICATION(S)
ELIGARD, LEUPROLIDE 2WK 1 MG/0.2 ML KIT, LEUPROLIDE 2WK 14 MG/2.8 ML KT, SYNAREL

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of male infertility

REQUIRED MEDICAL INFORMATION
For oncological indications: Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

For anemia associated with uterine leiomyomata (fibroids)
1. Documented trial, failure, intolerance or contraindication to at least 30 days of therapy with iron supplementation alone
AND
2. Documentation that Lupron® will be used in combination with iron supplementation

For uterine leiomyomata (fibroids)
1. Documentation that surgical removal of fibroids is planned within 4 months
AND
2. And one of the following, less invasive surgical methods will be employed:
a. Documentation of an enlarged uterus that will require a midline rather than transverse incision.
b. Documentation that shrinking the uterus or fibroids will allow for a vaginal hysterectomy rather than an abdominal procedure.

For endometriosis:
1. Documentation that other causes of gynecologic pain have been ruled out (e.g., irritable bowel syndrome, interstitial cystitis, urinary tract disorders)
2. For Synarel®: documented trial and failure to Lupron® with add-back progesterone therapy (such as norethindrone acetate) or Lupaneta® Pack.

Reauthorization
For Lupron® requires documentation that it will be used in combination with “add-back” progesterone therapy (e.g. norethindrone) to help prevent bone mineral density loss.

Reauthorization

For Synarel® and Zoladex® is not recommended. Treatment is only recommended for up to 6 months with these agents for endometriosis

For central precocious puberty
Note, a one-time dose may be approved for diagnostic purposes
For Initial Authorization:
1. Documentation of a history of early onset of secondary sexual characteristics (age 8 years and under for females or 9 years and under for males)
AND
2. Confirmation of diagnosis by one (1) of the following:
a. Pubertal response to a GnRH or GnRH analog (such as leuprolide) stimulation test [e.g., stimulated peak luteinizing hormone (LH) of approximately 4.0 to 6.0 IU/L and/or elevated ratio of LH/follicle-stimulating hormone at 0.66 or greater (reference range may vary depending on assay)]
b. Pubertal level of basal LH levels (0.3 IU/L or greater)
c. Bone age advanced one year beyond the chronological age
AND
3. For Synarel®: documented trial and failure or contraindication/intolerance to Lupron® and, either Triptodur® or Supprelin LA®

For Reauthorization:

1. Clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level), and
2. Documentation that hormonal and clinical parameters are being monitored periodically during treatment to ensure adequate hormone suppression.

Discontinuation of leuprolide should be considered before age 11 years for females and age 12 years for males. However, treatment discontinued at the appropriate age of onset of puberty should be at discretion of the treating provider.

For Gender Identity Disorder (GID):
1. Documented diagnosis of Gender Identity Disorder (GID) by a qualified mental health professional
2. Prescribed by or in consultation with an endocrinology specialist
3. Demonstration that puberty has progressed to a minimum of Tanner Stage 2 by:
a. Documentation of estrogen and testosterone levels
OR
b. Other sufficient evidence provided

For Endometrial thinning/dysfunctional uterine bleeding:
1. Documentation for use prior to endometrial ablation

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Anemia from fibroids: Authorization will be approved for up to 3 months (NO reauthorization)
Uterine leiomyomata (fibroids): Authorization will be approved for 4 months. No reauthorization
Endometriosis: For Lupron® and Lupaneta® Pack – authorization/reauthorization will be approved for up to 6 months (total of 12 months): For Synarel®/Zoladex® - initial authorization for up to 6 months and no reauthorization
CPP: Authorization/reauthorization will be approved for up to one year
GID: Authorization/reauthorization will be approved for up to one year
Endometrial Thinning/Dysfunctional Uterine Bleeding: Initial authorization for 2 months. No reauthorization.
Oncological Indications: Authorization/reauthorization will be approved for one year
In vitro fertilization: Authorization/reauthorization will be approved for one year

OTHER CRITERIA
N/A

HEPATITIS C- DIRECT ACTING ANTIVIRALS

MEDICATION(S)

EPCLUSA 400 MG-100 MG TABLET, HARVONI, LEDIPASVIR-SOFOSBUVIR, MAVYRET, SOFOSBUVIR-VELPATASVIR, SOVALDI, VIEKIRA PAK, VOSEVI, ZEPATIER

COVERED USES

N/A

EXCLUSION CRITERIA

All regimens containing a protease inhibitor (e.g. Mavyret®, Vosevi®) are not covered in patients with moderate to severe hepatic impairment (Child-Pugh B and C)

REQUIRED MEDICAL INFORMATION

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

For patients with cirrhosis only: Therapy must be prescribed by, OR the patient is in the process of establishing care with or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

COVERAGE DURATION

8 to 16 weeks based on FDA approved labeling.

OTHER CRITERIA

1. Documentation of confirmed diagnosis of chronic hepatitis C virus (HCV) infection with genotype AND
2. Documentation of HCV treatment history and response to therapy. Treatment failure with a NS5A inhibitor due to noncompliance will be reviewed on a case-by-case basis. AND
3. Documentation of cirrhosis status. In patients with clinical evidence of liver cirrhosis, Child-Pugh score is required AND
4. For coverage of non-preferred regimens, the prescriber must submit medical rational in support of its use. Coverage of non-preferred regimens will be reviewed based on evidence and medical necessity over preferred regimens

HEREDITARY ANGIOEDEMA

MEDICATION(S)
BERINERT, FIRAZYR, ICATIBANT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Required laboratory tests: Complement Component C4 and C1-Esterase inhibitor OR C1-Esterase Functional
Current patient weight

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Kalbitor® - 12 years and older
Firazyr® - 18 years and older
Ruconest® - 13 years and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an Immunologist or an Allergist.

COVERAGE DURATION
Initial authorization will be approved for up to 6 months. Reauthorization will be approved for up to 1 year.

OTHER CRITERIA
All of the following must be met:
1. Diagnosis of Hereditary Angioedema Types (HAE) I, II or III and one of the following clinical criteria:
a. Self-limiting, non-inflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours,
OR
b. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six hours,
OR
c. Recurrent laryngeal edema.

AND
2. One of the following:
A. For HAE Type I and Type II, documentation of at least two (2) complement studies taken at least one month apart with the patient in their basal condition and after the first year of life that show:
i. C4 is less than 50 percent of the lower limit of normal
AND
ii. one of the following:
a. C1-Inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal,
OR
b. C1-INH function is less than 50 percent of the lower limit of normal
B. For HAE with normal C1-INH or HAE Type III:
i. Confirmed Factor 12 (FXII) mutation
OR
ii. Positive family history for HAE AND attacks lack response with high dose antihistamines or corticosteroids.

For quantities exceeding the formulary quantity limit:
1. Documentation of frequent HAE attacks defined as greater than or equal to 2 attacks per month on average.
AND
2. Trial and failure, intolerance or contraindication to long-term prophylaxis with androgen therapy, such as danazol, stanozolol or oxandrolone.

QUANTITY LIMIT (subject to audit):

Berinert® - 2 injections per 30 days
Ruconest® - 2 injections per 30 days
Kalbitor® - 2 boxes (6 vials) per 30 days
Firazyr® - 3 injections (3 boxes, total of 9ml) per 30 days

HETLIOZ

MEDICATION(S)
HETLIOZ

COVERED USES
N/A

EXCLUSION CRITERIA
Sleep disorders other than Non-24.

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met:
1. Member is totally blind (i.e. no light perception)
2. Documented diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as characterized by:
a. Distinct pattern of sleeping and waking that drifts by a consistent time period every night
b. History of periods of insomnia, excessive sleepiness, or both, which alternate with short asymptomatic periods
3. Documented sleep study to exclude other sleep disorders
4. Documentation of clinically significant distress or impairment in social, occupational, and other important areas of functioning
5. Documented trial, failure, intolerance or contraindication to an adequate trial (at least 30 days) of melatonin
Reauthorization criteria:
1. Documentation of improvement in social, occupational, and other important areas of functioning AND
2. Documentation of entrainment to the 24-hour circadian period.
QUANTITY LIMIT:
Limited to 30 capsules per 30 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a sleep specialist.

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A

HORIZANT

MEDICATION(S)
HORIZANT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Restless Leg Syndrome:

Documentation of an adequate trial, failure, intolerance or contraindication to ropinirole AND pramipexole.

For Postherpetic Neuralgia:

Documentation of an adequate trial, failure, intolerance, or contraindication to gabapentin AND pregabalin.

QUANTITY LIMIT:

30 tablets per 30 days
Quantities of 60 tablets per 30 days will be approved for postherpetic neuralgia

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for up to one year.

OTHER CRITERIA
N/A

HP ACTHAR GEL

MEDICATION(S)
ACTHAR, H.P. ACTHAR

COVERED USES
N/A

EXCLUSION CRITERIA
All other indications beside infantile spasms are not considered medically necessary and are excluded for coverage.

REQUIRED MEDICAL INFORMATION
Body Surface Area
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization/reauthorization will be approved for one month.

OTHER CRITERIA
For infantile spasm: H.P. Acthar Gel® will be approved for one month of therapy at the following dose: 75 units/m2 injected intramuscularly twice daily

Reauthorization will require medical rationale for continuing treatment, as recommended treatment duration is for 2 weeks followed by two-week taper to avoid adrenal insufficiency.

HUMAN GROWTH HORMONES FOR ADULTS

MEDICATION(S)
NORDITROPIN, NORDITROPIN FLEXPRO, NORDITROPIN NORDIFLEX

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of idiopathic short stature.
Treatment of isolated growth hormone deficiency

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication is necessary.

May require the following specific tests depending on indication: Insulin Tolerance stimulation test (ITT), Glucagon Stimulation Test (GST), Insulin-like Growth Factor (IGF-1) levels, pituitary hormone levels (LH, FSH, TSH, ACTH), body weight, BMI, and/or genetic testing

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an endocrinologist.

COVERAGE DURATION
Authorization for short-bowel syndrome will be approved for a maximum of 4 weeks.
Authorization for AIDS wasting will be approved for a maximum of 12 months.
Initial authorization and reauthorization for other indications will be approved for up to 1 year.

OTHER CRITERIA
For growth hormone (GH) request other than Norditropin®, documentation that the patient has intolerance, FDA labeled contraindication, or hypersensitivity to Norditropin®
AND
Meet criteria listed below for each specific diagnosis:

1. For Growth Hormone Deficiency (GHD) in adults with GHD as a child: continuation of GH therapy will require one of the following criteria to be met:

a. Patient has organic disease (e.g., congenital defects, genetic defects) and one of the following:
i. At least three (3) pituitary hormone deficiencies (other than growth hormone) AND a low Insulin-like growth factor (IGF)-1 level [less than or equal to 2 Standard Deviations (SDS) below normal]. For appropriate IGF-1 levels by age check the Mayo Clinic Interpretive Handbook at http://www.mayomedicallaboratories.com/interpretive-guide/?alpha=I&unit_code=36365
ii. IGF-1 level below normal for age/sex and one of the following confirmatory stimulation tests:
1. Insulin Tolerance Test (ITT) with peak GH less than or equal to 5.0 mcg/L
2. Glucagon Stimulation Test (GST) with low peak GH based on body mass index (BMI), as follows:
a. BMI less than 25: Peak GH less than or equal to 3 mcg/L
b. BMI 25-30: Peak GH less than/equal to 1 mcg/L. For patients with high clinical suspicion of GHD, peak GH less than 3 mcg/L may be considered
c. BMI greater than/equal to 30: Peak GH less than/equal to 1 mcg/L
3. If both the ITT and GST are contraindicated, macimorelin with peak GH less than or equal to 2.8 mcg/L
b. Patient has suspected GHD from other causes and has the following confirmatory tests completed after GH therapy has been discontinued for at least one month:
1. IGF-1 level below normal for age/sex
2. One of confirmatory stimulation tests outlined in criterion 1.a.ii. above

2. For GHD in adults:

a. For patients with history of destructive lesions of the hypothalamic region (e.g., hypothalamic-pituitary tumors, surgery, or cranial irradiation, empty sella, pituitary apoplexy, traumatic brain injury, subarachnoid hemorrhage, Rathke's cleft cysts, autoimmune hypophysitis), all of the following:
i. Insulin-like growth factor (IGF)-1 level below normal for age/sex
ii. One of the confirmatory stimulation tests outlined in criterion 1.a.ii. above
b. For patients with organic disease of the hypothalamic region (e.g., congenital defects, genetic defects), one of the following:
i. At least three (3) pituitary hormone deficiencies (other than growth hormone) AND an low IGF-1 level (less than or equal to 2 SDS below normal)
ii. IGF-1 level below normal for age/sex and one of the confirmatory stimulation tests outlined in criterion 1.a.ii. above

3. Reauthorization for GHD requires evidence of improved quality of life, good tolerability and annual documentation of IGF-1 levels with appropriate dosage adjustments. (GH requirements often decrease with age).

4. For Acquired Immunodeficiency Syndrome (AIDS) Wasting, all of the following criteria must be met:

a. Involuntary loss of at least 10% body weight

b. Absence of other related illnesses contributing to weight loss
c. Documented failure, intolerance, or contraindication to appetite stimulants and/or other anabolic agents.

5. For Short Bowel Syndrome, all of the following criteria must be met

a. Ability to ingest solid food
b. Must be receiving specialized nutrition support (i.e. high carbohydrate, low-fat diet, enteral feedings, parenteral nutrition)

QUANTITY LIMITS:

For GHD: Initial dose will be approved at no more than 0.04 mg/kg body weight/week, or no more than 0.2 mg/day for obese and/or diabetic patients.

Reauthorization dose will be approved at no more than 0.08 mg/kg body weight/week.

HUMAN GROWTH HORMONES FOR PEDIATRICS

MEDICATION(S)
NORDITROPIN, NORDITROPIN FLEXPRO, NORDITROPIN NORDIFLEX

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of idiopathic short stature.

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

May require the following depending on indication: height standard deviation score, growth velocity, GH stimulation tests, IGF-1 levels, IGFBP-3 levels, pituitary hormone levels (LH, FSH, TSH, ACTH), status of epiphyses, and/or genetic testing.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by a pediatric endocrinologist or pediatric nephrologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for up to 1 year.

OTHER CRITERIA
For Medicaid: Coverage is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services

For initial authorization:
I. Documented evidence of open epiphyses
AND
II. For non-preferred growth hormone (GH) request, documentation that the patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to preferred growth hormone product(s). Please see Table 1 for preferred products.
AND

III. Meet criteria listed below for each specific diagnosis:
A. Growth Hormone Deficiency (GHD): must meet criteria for one of the following:
i. Newborn with hypoglycemia and both of the following criteria:
1. Serum GH level less than or equal to 5 mcg/L
2. One of the following:
a. One additional pituitary hormone deficiency (other than growth hormone): or
b. Classical imaging triad (ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk)
ii. Patient with extreme short stature [defined as height standard deviation score (SDS) of more than 3 SDS below the mean for chronological age/sex] and all of the following:
1. Insulin-like growth factor (IGF)-1 level at least 2 SDS below normal
2. Insulin-like growth factor binding protein-3 (IGFBP-3) at least 2 SDS below normal
3. Delayed bone age, defined as bone age that is 2 SDS below the mean for chronological age
iii. Patient has pituitary abnormality (secondary to a congenital anomaly, tumor, or irradiation) and meets both of the following criteria:
1. One additional pituitary hormone deficiency (other than growth hormone)
2. Evidence of short stature/growth failure by one of the following:
a. Height standard deviation score (SDS) of more than 3 SD below the mean for chronological age/sex
b. Height for age/sex is below the 3rd percentile (or greater than 2 SD below the mean) AND untreated growth velocity (GV) is below the 25th percentile (must have at least 1 year of growth data)
c. Severe growth rate deceleration (GV measured over one year of more than 2 SD below the mean for age/sex) Standardized Height and Weight Calculator
iv. All other patients with suspected GHD must me all of the following criteria:
1. Evidence of short stature/growth failure using criteria III.A.iii.2. above
2. Documented biochemical GHD by one of the following:
a. Two GH stimulation tests (using a provocative agent such as arginine, clonidine, glucagon, insulin or levodopa) showing peak GH concentrations of less than 10 ng/ml
b. One GH stim test level less than 15ng/ml and insulin-like growth factor (IGF)-1 and IGFBP-3 levels below normal for bone age/sex
B. Prader-Willi Syndrome (PWS)
i. Documented confirmation of diagnosis through genetic testing
C. Turner’s Syndrome (TS)
i. Diagnosis confirmed by genetic testing
AND
ii. Evidence of short stature/growth failure meeting one of the criteria above (III.A.iii.2.)
D. Noonan Syndrome
i. Diagnosis confirmed by genetic testing or made by pediatric endocrinologist based on clinical features (i.e. classic facies, congenital heart disease, abnormal skeletal features, factor XI deficiency, hearing loss, developmental delays),
AND
ii. Evidence of short stature/growth failure meeting one of the criteria above (III.A.iii.2.)

E. Chronic Renal Insufficiency
i. Other causes of growth failure have been ruled out and nutritional status has been optimized
AND
ii. Evidence of short stature/growth failure meeting one of the criteria above (III.A.iii.2.)
iii. Note: Authorization will be withdrawn after transplantation.
F. Small for Gestational Age (SGA)
i. Birth weight and/or length at least three SDs below the mean for gestational age
AND
ii. Failure to reach catch-up growth by two years of age, defined as height at least two SDs below the mean for age/sex

For Reauthorization, all of the following criteria has been met:

I. Evidence of growth velocity (GV) of greater than 2.5 cm/year
AND
II. Evidence of open epiphyses

IL-5 INHIBITORS - CINQAIR FASENRA, NUCALA - MEDICAL BENEFIT

MEDICATION(S)

FASENRA PEN, NUCALA 100 MG/ML AUTO-INJECTOR, NUCALA 100 MG/ML SYRINGE

COVERED USES

N/A

EXCLUSION CRITERIA

Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.

REQUIRED MEDICAL INFORMATION

For initial authorization, must meet all of the following criteria:

For eosinophilic asthma:

1. Documentation of eosinophilic asthma by one of the following:

a. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months

b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids

2. Documentation of treatment with maximally tolerated dose of medium to high –dose inhaled corticosteroid plus a long-acting inhaled beta2-agonist and has been compliant to therapy in the past 3 months (this may be verified by pharmacy claims information)

3. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following:

a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5

b. At least two (2) asthma exacerbations requiring oral systemic corticosteroids in the last 12 months

c. At least one (1) asthma exacerbation requiring hospitalization, emergency room or urgent care visit

For Eosinophilic Granulomatosis with Polyangiitis (EGPA):

1. Request is for Nucala®

2. History or presence of asthma

3. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter

4. At least two of the following clinical findings:

a. Biopsy evidence of eosinophilic vasculitis

b. Motor deficit or nerve conduction abnormality

c. Pulmonary infiltrates

d. Sinonasal abnormality

e. Cardiomyopathy

f. Glomerulonephritis

g. Alveolar hemorrhage

h. Palpable purpura

i. Positive test for ANCA
5. Documentation of one of the following
a. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous 2 years while receiving at least 7.5 mg/day prednisone (or equivalent)
OR
b. Failure to achieve remission following a standard induction regimen administered for at least 3 months OR recurrence of symptoms of EGPA while tapering of glucocorticoids
i. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil

Reauthorization:
Documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

QUANTITY LIMIT:
Nucala® syringe and auto injector: 1 per 28 days (quantities of 3 per 28 days are approvable for EGPA)
Fasenra® Pen: 1 per 56 days (quantities of 1 per 28 days will be allowed for 3 month for initial loading dose)

AGE RESTRICTION
Nucala®: Approved for 6 years of age or older
Cinqair®: Approved for 18 years of age or older
Fasenra®: Approved for 12 years of age or older

PRESCRIBER RESTRICTION
For eosinophilic asthma: must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)
For Eosinophilic Granulomatosis with Polyangiitis: must be prescribed by or in consultation with a pulmonologist, neurologist, or rheumatologist

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A

INCRELEX

MEDICATION(S)
INCRELEX

COVERED USES
N/A

EXCLUSION CRITERIA
Subjects with secondary forms of Insulin-like growth factor (IGF)-1 deficiency:
• GH deficiency
• Malnutrition
• Hypothyroidism
• Chronic treatment with pharmacologic doses of anti-inflammatory steroids
Concurrent use of growth hormone therapy
Malignant neoplasia

REQUIRED MEDICAL INFORMATION
Plasma IGF-1 activity, blood glucose, plasma insulin, connecting peptide (C-peptide), glycosylated hemoglobin, serum electrolytes, liver enzymes.

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
For Severe primary IGF-1 deficiency:

1. Height standard deviation score of less than or equal to -3.0
AND
2. Basal insulin-like growth factor (IGF)-1 standard deviation score of less than or equal to -3.0

AND
3. Normal or elevated growth hormone (GH) levels.
AND
4. Documentation of open epiphyses by bone radiograph

For Growth hormone (GH) gene deletion

1. Documentation of open epiphyses by bone radiograph
AND
2. Patient has developed neutralizing antibodies to growth hormone

Reauthorization will require evidence that the medication remains effective, growth velocity is above 2.0 cm/year, evidence of open epiphyses, and documentation of expected adult height goal that is not yet obtained.

INFERTILITY AND RELATED HORMONE MEDICATIONS

MEDICATION(S)
CRINONE, ENDOMETRIN

COVERED USES
N/A

EXCLUSION CRITERIA
The treatment of infertility is a benefit exclusion for the Oregon Health Plan
Medications used in all forms and variations for Assisted Reproductive Technology (ART) are excluded from coverage, except for those groups with the benefit covering ART [including in vitro fertilization (IVF)].

REQUIRED MEDICAL INFORMATION
I. For treatment of infertility (subject to benefit limitations) must meet criteria for specific cause of infertility as follows:
1. For females with anovulation due to hypothalamic-pituitary failure, gonadotropins may be covered if the following criteria is met:
i. Low pre-treatment level of serum estradiol concentrations AND
ii. Low or low-normal serum follicle-stimulating hormone (FSH) or luteinizing hormone (LH) levels AND
iii. Normal body mass index achieved (defined as BMI greater than 18.5) if anovulation is documented to be caused by low body weight
2. For females with anovulation associated with polycystic ovarian syndrome (PCOS), gonadotropins may be covered if one (1) of the following criteria is met:
i. Documented failure, contraindication or intolerance to clomiphene (failure defined as failure to conceive after at least three cycles) OR
ii. Documented failure, contraindication or intolerance to letrozole
(failure defined as failure to conceive after at least three cycles)
3. For hyperprolactinemia in females or males, gonadotropins may be covered if the all the following criteria are met:
i. Documented failure, contraindication, or intolerance to dopamine agonists (e.g., bromocriptine or cabergoline) AND
ii. For females, documented failure, contraindication, or intolerance to clomiphene (failure defined as failure to conceive after at least three cycles)
4. For females with Primary Ovarian Insufficiency (POI) or diminished ovarian reserve, gonadotropins may be covered as part of assisted reproductive technology (ART), subject to IVF benefit, if the following criteria is met:
i. Both low pre-treatment serum estradiol levels AND elevated follicle stimulating hormone (FSH) levels OR
ii. Low antral follicle count (AFC), based on specific laboratory reference range (usual cutoff is less than 6)

5. For females with anatomical abnormalities related to the fallopian tube, uterus (i.e. endometriosis, intrauterine adhesions), or cervix or couples with unexplained infertility, gonadotropins may be covered if one (1) of the following criteria is met:
i. Documented failure, contraindication or intolerance to clomiphene (failure defined as failure to conceive after at least three cycles) OR
ii. Documented failure, contraindication or intolerance to letrozole (failure defined as failure to conceive after at least three cycles) OR
iii. Documentation of irreversible cause for infertility (i.e. bilateral tubal obstruction, inoperable uterine abnormality, endometriosis)
6. For male factor infertility, requests for gonadotropins may be covered if the following criteria is met:
i. Documentation of low sperm production or sperm defects OR
ii. Documentation of anatomical abnormality or obstruction, congenital or developmental disorder, or acquired disorder of the testes
II. For maintenance of pregnancy, progesterone formulations may be approved if the following criteria is met:
1. Documentation of current pregnancy OR
2. Documentation that patient has history of prior pregnancy loss
III. For males with cryptorchidism, human chorionic gonadotropin (hCG) therapy may be approved if the following criteria is met:
1. Patient is between the ages of 4 and 9 years AND
2. Documentation that cryptorchidism is not due to anatomic obstruction

AGE RESTRICTION
Female must be less than 45 years of age for treatment of infertility unless being used for ART.

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gynecologist, urologist, or endocrinologist.

COVERAGE DURATION
Authorization will be approved for one year

OTHER CRITERIA
N/A

INJECTABLE ANTI-CANCER MEDICATIONS

MEDICATION(S)
ACTIMMUNE, SYLATRON, SYLATRON 4-PACK, SYNRIBO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
2. For Herceptin Hylecta® (trastuzumab and hyaluronidase-oysk): Documentation of trial and failure, intolerance, or contraindication to trastuzumab
3. For Phesgo® (trastuzumab, pertuzumab, hyaluronidase-zzxf): Documentation of trail and failure, intolerance, or contraindication to either trastuzumab or pertuzumab as individual agents

For reauthorization:
Documentation of adequate response to the medication must be provided.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with an Oncologist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 3 months up to 1 year.

OTHER CRITERIA

INSOMNIA AGENTS

MEDICATION(S)
RAMELTEON, ROZEREM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of trial and failure, contraindication or intolerance to two of the following: zolpidem, zaleplon, temazepam, and/or eszopiclone.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A

INTRANASAL MEDICATIONS

MEDICATION(S)
OMNARIS, VERAMYST, ZETONNA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Documented adequate trial and failure, intolerance or contraindication to fluticasone propionate nasal spray (generic Flonase®), either prescription or OTC.
AND
2. Documented adequate trial and failure, intolerance or contraindication to one (1) additional formulary or over-the-counter corticosteroid intranasal medication used for the treatment of allergic rhinitis [e.g. flunisolide nasal spray, triamcinolone nasal spray, mometasone (Nasonex®) nasal spray]

Note: An adequate trial is defined as at least one month of therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
N/A

JUXTAPID/KYNAMRO

MEDICATION(S)
JUXTAPID

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
LDL level or genetic confirmation of Homozygous Familial Hypercholesterolemia
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board certified lipidologist

COVERAGE DURATION
Initial authorization will be approved for up to six months. Reauthorization will be approved for up to 1 year.

OTHER CRITERIA
All of the following must be met:
1. Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) as evidenced by:
a. Genetic confirmation OR
b. Untreated LDL-C greater than 500 mg/dl and xanthoma OR
c. Both parents are heterozygous FH AND
2. One of the following:
a. Intolerable muscle side effects or biomarker changes (such as elevations of creatinine kinase) to at least two statins that decrease or resolve after discontinuation of therapy with statin. AND
3. An adequate trial and failure (3 months of therapy), contraindication or intolerance to the use of ezetimibe (Zetia®) AND
4. An adequate trial and failure (3 months of therapy), contraindication or intolerance to the use of a formulary PCSK-9 inhibitor

Reauthorization

Must show documentation that LDL-C has decreased from pre-treatment levels.

KETOROLAC INTRAMUSCULAR INJECTION

MEDICATION(S)

KETOROLAC 15 MG/ML CARPUJECT, KETOROLAC 15 MG/ML ISECURE SYR, KETOROLAC 15 MG/ML SYRINGE, KETOROLAC 15 MG/ML VIAL, KETOROLAC 30 MG/ML CARPUJECT, KETOROLAC 30 MG/ML ISECURE SYR, KETOROLAC 30 MG/ML SYRINGE, KETOROLAC 30 MG/ML VIAL, KETOROLAC 60 MG/2 ML CARPUJECT, KETOROLAC 60 MG/2 ML SYRINGE, KETOROLAC 60 MG/2 ML VIAL

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. Request is for one of the following:
a. Moderately severe acute pain not manageable by oral NSAIDs
b. Migraine pain not manageable by a formulary triptan (e.g. frovatriptan, naratriptan, rizatriptan, sumatriptan, Zomig® nasal spray)
AND
2. Documentation that patient does not have a diagnosis of peptic ulcer disease, gastrointestinal bleed, advanced renal failure, or coagulation disorder
AND
3. Documentation that ketorolac tromethamine use will not exceed a total of 5 days of treatment (Note: The total combined duration of use of oral ketorolac tromethamine and ketorolac tromethamine injection should not exceed 5 days)

Reauthorization criteria:
1. Documentation of a positive clinical response to the requested therapy
2. Documentation that ketorolac tromethamine use will not exceed a total of 5 days of treatment (Note: The total combined duration of use of oral ketorolac tromethamine and ketorolac tromethamine injection should not exceed 5 days)

QUANTITY LIMIT:

15 mg/mL vials or syringes – 20 mL per 28 days
30 mg/mL vials or syringes – 20 mL per 28 days
60 mg/2 mL vials or syringes – 10 mL per 28 days

AGE RESTRICTION

Approved in 17 years and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA

N/A

KOSELUGO

MEDICATION(S)
KOSELUGO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. Documentation of inoperable neurofibromatosis type 1 (NF1) plexiform neurofibroma (PN) (defined as one that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN)
2. Patient has significant morbidity related to the target PN (i.e. motor dysfunction, pain, airway dysfunction, visual impairment, and bladder/bowel dysfunction)

For reauthorization:

Documentation of adequate response to the medication must be provided.

AGE RESTRICTION
Approved for ages 2 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with an oncologist, neuro-oncologist, neurologist, neurosurgeon or a provider at a neurofibromatosis center

COVERAGE DURATION
Initial authorization will be approved for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A

KUVAN

MEDICATION(S)
KUVAN, SAPROPTERIN DIHYDROCHLORIDE

COVERED USES
N/A

EXCLUSION CRITERIA
• Doses greater than 20mg/kg/day will not be approved.
• Use in combination with Palynziq® (pegvalise-pqpz)

REQUIRED MEDICAL INFORMATION
Average blood Phe levels.
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a specialist in metabolic disorders

COVERAGE DURATION
Initial authorization for 2 months. Reauthorization for 12 months.

OTHER CRITERIA
Must meet both of the following criteria for initial authorization:
1. Diagnosis of phenylketonuria (PKU)
AND
2. Documentation the requested medication will be used in conjunction with a phenylalanine (Phe)-restricted diet
AND
3. Documentation that the patient’s pre-treatment phenylalanine blood levels measured within 90 days prior to starting therapy is above 6 mg/dL (360 micromol/L) in children less than 12 years of age, or above 10 mg/dL (600 micromol/L) for ages 12 and older.

For Reauthorization:

1. Documentation that average blood Phe level decreased by at least 30% for initial reauthorization and remain 30% below pretreatment baseline for continued authorization thereafter
AND
2. Documentation of continued dietary Phe-restriction

LIDOCAINE PATCH

MEDICATION(S)
LIDOCAINE 5% PATCH, LIDODERM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For post-herpetic neuralgia and cancer-related neuropathic pain:
1. Documented trial and failure, contraindication or intolerance to gabapentin or pregabalin

For diabetic peripheral neuropathy:
1. Documentation of trial and failure, contraindication or intolerance to a TCA or duloxetine
AND
2. Documentation of trial and failure, contraindication or intolerance to gabapentin or pregabalin

Reauthorization will require documentation submitted showing adequate response to therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For post-herpetic neuralgia and cancer-related neuropathic pain: Initial authorization for 3 months. Reauthorization for 6 months.
For diabetic peripheral neuropathy: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
For post-herpetic neuralgia and cancer-related neuropathic pain:
1. Documented trial and failure, contraindication or intolerance to gabapentin or pregabalin

For diabetic peripheral neuropathy:
1. Documentation of trial and failure, contraindication or intolerance to a TCA or duloxetine

AND

2. Documentation of trial and failure, contraindication or intolerance to gabapentin or pregabalin

Reauthorization will require documentation submitted showing adequate response to therapy.

LONG ACTING OPIOIDS

MEDICATION(S)

AVINZA, BUPRENORPHINE, BUTRANS, EXALGO, HYDROCODONE BITARTRATE ER, HYDROMORPHONE ER, MORPHINE SULFATE ER 120 MG CAP, MORPHINE SULFATE ER 30 MG CAP, MORPHINE SULFATE ER 45 MG CAP, MORPHINE SULFATE ER 60 MG CAP, MORPHINE SULFATE ER 75 MG CAP, MORPHINE SULFATE ER 90 MG CAP, OXYMORPHONE HCL ER, XTAMPZA ER, ZOHYDRO ER

COVERED USES

N/A

EXCLUSION CRITERIA

• As needed (prn) use.
• For treatment of acute pain such as recent injury, sprain, strain, surgery, migraines or headaches.

REQUIRED MEDICAL INFORMATION

For patients initiating therapy with a long-acting opioid therapy:
1. The following indication-specific criteria must be met:
a. For cancer pain, palliative care with a terminal diagnosis, sickle cell disease or severe burns:
i. Documentation of trial and failure of scheduled short-acting opioid therapy AND
ii. Documentation of trial and failure, contraindication, or intolerance to long-acting morphine sulfate therapy
b. For chronic pain:
i. Documentation of chronic non-malignant pain (lasting longer than 3 months) that is severe enough to require around-the-clock analgesic therapy AND
ii. Documentation of trial and failure of scheduled short-acting opioid therapy AND
iii. Documentation of trial and failure, contraindication, or intolerance to long-acting morphine sulfate therapy AND
iv. Documentation of trial and failure of non-opioid therapies or these therapies are being used in conjunction with opioid therapy or these therapies are not appropriate (non-opioid therapies include but are not limited to: nonsteroidal anti-inflammatory drugs [NSAIDs], tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors [SNRIs], anticonvulsants, exercise therapy, acupuncture, weight loss, cognitive behavioral therapy)
v. Documentation of a signed pain management agreement between the prescriber and patient
2. The following drug-specific criteria must be met in addition to the above criteria:
a. For Oxycontin®: Documentation of trial and failure of Xtampza ER® (oxycodone extended-release (ER) capsules)
b. For Belbuca®: Documentation of trial and failure of Butrans® (buprenorphine transdermal)
c. For morphine sulfate sustained-release (SR) capsules (Kadian/Avinza®): medical rationale for requiring

the use of the requested formulation of long-acting morphine over morphine sulfate ER tablets (generic for MS Contin®)

For patients established on therapy with a long-acting opioid therapy
1. The following indication-specific criteria must be met:
a. For cancer pain, palliative care with a terminal diagnosis, sickle cell disease or severe burns:
i. Documentation of positive response to therapy
b. For chronic pain:
i. Documentation that shows an improvement in pain control and level of functioning. If no improved pain control and level of functioning, rationale is provided for continued use of opioid therapy or a plan for taper/discontinuation AND
ii. Documentation of a signed pain management agreement between the prescriber and patient that is reviewed at least annually
2. The following drug-specific criteria must be met in addition to the above criteria:
a. For Oxycontin®: Documentation of trial and failure of Xtampza ER® (oxycodone extended-release capsules)

QUANTITY LIMIT:

Opioid doses greater than 90 mg Morphine Milligram Equivalent (MME) per day in the treatment of chronic non-malignant pain requires additional prior authorization. See Policy Maximum Allowable Opioid Dose (#ORPTCANA031) for clinical coverage criteria.

Quantity limits for specific products are outlined in Appendix A. Coverage for quantities above these limits will require medical rationale for using outside of FDA dosing recommendations (e.g. more than twice per day for Xtampza ER®)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be for up to one year

OTHER CRITERIA
N/A

LOTRONEX (ALOSETRON HCL TABLETS)

MEDICATION(S)
ALOSETRON HCL, LOTRONEX

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with constipation

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Age 18 years or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gastroenterologist. Please note that prescriber should comply with the requirements of the Alosetron REMS Program

COVERAGE DURATION
Initial authorization will be for 60 days (FDA recommends to discontinue alosetron in patients who fail to achieved adequate control of IBS symptoms after 4 weeks of treatment).

Reauthorization will be approved for 6 months

OTHER CRITERIA
For initiation, all of the following must be met:
1. Patient is female
2. Documentation of severe diarrhea-predominant irritable bowel disease (IBS-D), defined as having at least one (1) of the following symptoms for at least six months:
a) Frequent and severe abdominal pain/discomfort
b) Frequent bowel urgency or fecal incontinence
c) Disability or restriction of daily activities due to IBS-D
3. Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of each of the following standard therapies:

a) Regular use of dietary fiber supplementation (e.g. cereal, citrus, fruits or legumes)
b) Regular use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids)
c) Opioid mu receptor agonists [e.g., loperamide (Imodium?), diphenoxylate (Lomotil?)]
d) Anti-spasmodic agent (e.g., dicyclomine)
e) Tricyclic antidepressants (e.g., amitriptyline)

For reauthorization:

1. Documentation of response to therapy, defined as reduction in frequency and urgency of bowel movements, reduction in abdominal pain/discomfort, or improved quality of life
2. Absence of constipation during treatment

MAVENCLAD

MEDICATION(S)
MAVENCLAD

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with other disease modifying agents for MS

REQUIRED MEDICAL INFORMATION
Documented trial and failure, intolerance, or contraindication to two (2) conventional therapies for multiple sclerosis.

AGE RESTRICTION
Approved for patients age 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist

COVERAGE DURATION
May be approved for up to 2 years, ensuring the cumulative duration of therapy does not exceed 2 years in a lifetime Treatment beyond 2 years will not be authorized.

OTHER CRITERIA
N/A

MEDICATIONS FOR RARE INDICATIONS - ORPHAN DRUGS

MEDICATION(S)
BUPHENYL, CARBAGLU, CERDELGA, MIGLUSTAT, RAVICTI, SODIUM PHENYLBUTYRATE, ZAVESCA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with a specialist in the respective disease state.

COVERAGE DURATION
Initial authorization will be approved for one year and reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
Both of the following must be met:
1. Confirmation of FDA-labeled indication (appropriate lab values and/or genetic tests must be submitted): AND
2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis (e.g., high-quality peer reviewed literature, guidelines, other clinical information)
REAUTHORIZATION CRITERIA:
Both of the following must be met:
1. Documentation of successful response to therapy: AND
2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis (e.g., high-quality peer reviewed literature, guidelines, other clinical information)

MEPRON

MEDICATION(S)
ATOVAQUONE, MEPRON

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for 13 years and older.

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an Infectious Disease specialist.

COVERAGE DURATION
For PCP: Initial authorization and reauthorization will be approved for one year.
For Babesiosis: Initial authorization approved for 10 days for one treatment course.

OTHER CRITERIA
For pneumocystis pneumonia (PCP): Documented trial, failure, intolerance or contraindication to trimethoprim/ sulfamethoxazole (TMP-SMX)
For Babesiosis:
1. Laboratory confirmation of infection (e.g., blood smear, PCR)
2. Documentation that the patient is experiencing symptoms of disease such as hemolytic anemia, thrombocytopenia, and/or flu-like symptoms
3. Confirmation that the patient will be taking atovaquone with azithromycin

Reauthorization:
Most patients are able to be successfully treated after one 7-10-day treatment course. Subsequent treatments will require laboratory confirmation of continued infection (e.g., blood smear, PCR).

MIACALCIN

MEDICATION(S)
MIACALCIN 400 UNIT/2 ML VIAL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For the treatment or prevention of osteoporosis:
Patient has indication for treatment as evidenced by one (1) of the following:
1. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures
2. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 and high risk for fracture, defined as one (1) of the following:
a. Age more than 80 years
b. Chronic glucocorticoid use
c. Documented increased fall risk
3. Patient has a spine or hip BMD T-score less than or equal to -2.5 and one (1) of the following:
a. Documented failure to anti-resporptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
b. Documented contraindication or intolerance to therapy with all of the following:
i. Denosumab,
ii. Oral bisphosphonate (e.g., alendronate), or
iii. IV bisphosphonate therapy (i.e., zoledronic acid)
4. Patient has a spine or hip BMD T-score between -2.5 and -1.0 and BOTH of the following:
a. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%
b. One (1) of the following:
i. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
ii. Documented contraindication or intolerance to therapy with all of the following:
1. Denosumab
2. Oral bisphosphonate (e.g., alendronate)
3. IV bisphosphonate therapy (i.e., zoledronic acid)

For Treatment of Paget’s Disease:

1. Documentation of trial and failure of bisphosphonate therapy. Failure is defined as no improvement in pain and/or function.
2. Documented contraindication or intolerance to therapy with both of the following:
a. Oral bisphosphonate (e.g., alendronate)
b. IV bisphosphonate therapy (i.e., zoledronic acid)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial approval and renewal for 1 year.

OTHER CRITERIA
N/A

MYALEPT

MEDICATION(S)
MYALEPT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Metabolic parameters (HbA1c, triglyceride levels, fasting insulin levels)
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
1. Diagnosis of congenital or acquired generalized lipodystrophy (i.e., not related to HIV, nor obesity not related to leptin deficiency) AND
2. Documentation of at least one of the following metabolic complications of leptin deficiency:
a. Diabetes mellitus
b. Triglyceride levels greater than or equal to 200 mg/dL
c. Increased fasting insulin levels greater than or equal to 30 units/mL AND
3. Documentation that the patient has not had a response to current standards of care for lipid and diabetic management.
Reauthorization:
Requires documentation of response to therapy as indicated by one of the following:
a. Sustained reduction in hemoglobin A1c level from baseline
b. Sustained reduction in triglyceride levels from baseline

NATPARA

MEDICATION(S)
NATPARA

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use of Natpara® with alendronate

REQUIRED MEDICAL INFORMATION
Corrected serum-albumin calcium levels

Serum levels of 25 OH vitamin D

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
Initial authorization for 6 months and reauthorization will be approved for 1 year

OTHER CRITERIA
1. Patient must be diagnosed with permanent/chronic hypoparathyroidism (i.e. not acute post-surgical hypoparathyroidism)
AND
2. Documentation of failure to maintain serum-albumin corrected calcium with the chronic use of calcium and vitamin D supplementation for a minimum of 6 months.
AND
3. Documentation that Natpara® will be used concurrently with calcium and vitamin D.
AND
4. Confirm serum albumin corrected calcium is above 7.5 mg/dL (1.9 mmol/L)
AND

5. Confirm serum 25-hydroxyvitamin D is greater than or equal to 30 ng/mL (75 nmol/L)

Reauthorization requires annual documentation of regular monitoring of serum calcium levels with appropriate dosage adjustments to meet patient specific goal.

QUANTITY LIMIT:

28 doses per 28 days
Each package contain 2 cartridges (14 doses per cartridge: 28 doses total)

NON-PREFERRED INSULINS

MEDICATION(S)

APIDRA, APIDRA SOLOSTAR, INSULIN ASPART, INSULIN ASPART FLEXPEN, INSULIN ASPART PENFILL, INSULIN ASPART PROT-INSULN ASP, NOVOLIN 70-30, NOVOLIN N, NOVOLIN R, NOVOLOG, NOVOLOG FLEXPEN, NOVOLOG MIX 70-30, NOVOLOG MIX 70-30 FLEXPEN

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. Documented trial, failure, intolerance or contraindication to the preferred formulary alternative(s) for the requested insulin product, as outlined below:
- Preferred alternative for Novolog (and biosimilars), Admelog, Apidra, Fiasp, Lyumjev is Humalog (may require dosage adjustments for some)
- Preferred alternative for Novolin N is Humulin N (same dosing)
- Preferred alternative for Novolin 70/30 is Humulin 70/30 (same dosing)
- Preferred alternative for Novolin R is Humulin R (same dosing)
- Preferred alternative for Novolog Mix is Humalog Mix (may require dosage adjustments)

OR

2. A supporting statement from the provider outlining medical rationale for inability to use the preferred agents above (such as member is established on an insulin pump with another product or patient has a physical or a mental disability that would prevent them from using a preferred insulin agent)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA

N/A

NOURIANZ

MEDICATION(S)
NOURIANZ

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with a major psychotic disorder

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Confirmed diagnosis of Parkinson’s Disease
2. Documentation the patient is experiencing OFF episodes with current use of oral carbidopa/levodopa therapy
3. Documentation of attempts to adjust dosing and formulation of carbidopa/levodopa to manage OFF symptoms
4. Documentation that at least two other agents have been used as adjunctive therapy with carbidopa/levodopa (e.g. dopamine agonist, COMT inhibitor, or MAO-B inhibitor) to reduce number and frequency of OFF episodes

Reauthorization: Documentation that patient has had a positive response to therapy, such as decrease in number, duration or severity of OFF episodes.

QUANTITY LIMIT:
Istradefylline oral tablet (Nourianz®) 20 mg and 40 mg: 1 tablet per day

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist

COVERAGE DURATION
Initial authorization will be approved for 6 months, reauthorization will be approved for 1 year

OTHER CRITERIA
N/A

NUCYNTA

MEDICATION(S)
NUCYNTA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Trial and failure of tramadol
AND
2. Documentation of trial and failure of a formulary short-acting opioid analgesic (such as oxycodone)

AGE RESTRICTION
Approved for 18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for up to one year.

OTHER CRITERIA
N/A

NUCYNTA ER

MEDICATION(S)
NUCYNTA ER

COVERED USES
N/A

EXCLUSION CRITERIA
As needed (prn) use

REQUIRED MEDICAL INFORMATION
For Chronic Pain:
1. Documentation of trial and failure, contraindication, or intolerance to:
a. Extended-release tramadol
AND
b. Extended-release morphine sulfate
2. Documentation of persistent pain (expected to last longer than 3 months)
For Chronic Pain associated with diabetic peripheral neuropathy (DPN):
1. Documentation of trial and failure, contraindication, or intolerance to:
a. Gabapentin or pregabalin
AND
b. One tricyclic antidepressant (TCA), selective serotonin reuptake inhibitor (SSRI) or serotonin–norepinephrine reuptake inhibitor (SNRI)

QUANTITY LIMIT:
Limit to 60 tablets per 30 days.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for up to 1 year

OTHER CRITERIA
N/A

NUEDEXTA

MEDICATION(S)
NUEDEXTA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a neurologic disease or brain injury (such as traumatic brain injury, stroke, dementia, multiple sclerosis, amyotrophic lateral sclerosis (ALS), or Parkinson’s disease).

Reauthorization: Documentation of response to therapy, defined as a reduction in episodes of laughing, crying, and/or emotional lability.

QUANTITY LIMIT:

2 capsules per day

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A

OCALIVA

MEDICATION(S)
OCALIVA

COVERED USES
N/A

EXCLUSION CRITERIA
NASH patients with liver cirrhosis (F4)

REQUIRED MEDICAL INFORMATION
- Laboratory monitoring: total bilirubin (tBili), alkaline phosphatase (ALP), and aspartate aminotransferase (AST)
- Child-Pugh class
- For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist.

COVERAGE DURATION
Initial authorization will be approved for 4 months. Reauthorization will be approved for one year.

OTHER CRITERIA
For the diagnosis of primary biliary cholangitis:
1. Confirmed diagnosis of primary biliary cholangitis as evidence by two (2) of the following criteria:
a. Elevated alkaline phosphatase (ALP) [above the upper limit of normal (ULN) as defined by laboratory reference values]
b. Presence of antimitochondrial antibody (AMA)
c. Histologic evidence of primary biliary cirrhosis from liver biopsy
AND
2. Both of the following:
a. Use of ursodiol for a minimum of 6 months and has had an inadequate response according to prescribing physician
AND

b. Documentation that the medication will be used in combination with ursodiol, unless patient is unable to tolerate ursodiol
AND
3. Dose is appropriate based on an assessment of hepatic function (Child-Pugh class). If Child-Pugh B or C, start at 5mg once weekly (can be increased if needed to a maximum of 10mg twice weekly)

Reauthorization Criteria:

1. Maintenance of biochemical response [i.e. alkaline phosphatase (ALP) less than or equal to 1.67 times ULN, total bilirubin (tBili) less than or equal to ULN, and ALP decrease of at least 15%]
2. Documentation that ursodiol will be continued, if tolerated
3. Hepatic function is assessed at least annually. If Child-Pugh B or C, dose should not exceed 10mg twice weekly)

For the diagnosis of non-alcoholic steatohepatitis (NASH):
1. Provider attestation that secondary causes of fatty liver have been ruled out. Common causes of fatty liver include excessive alcohol consumption, hepatitis C, long- term use of a steatogenic medication, Wilson's Disease and malnutrition (See Appendix 1)
AND
2. One of the following:
A. Histologic evidence of NASH from liver biopsy
OR
B. Presence of hepatic steatosis (HS) or fatty liver that is greater than or equal to 5% as evidence by vibration controlled transient elastography (VCTE: FibroScan®) or magnetic resonance elastography (MRE).
AND
3. Documentation of advanced fibrosis based on one of the following tests:
A. Metavir score of F2 or F3 based on liver biopsy or imaging study (i.e.,FibroScan® or MRE)
OR
B. One of the following:
i. NAFLD score greater than 0.645
ii. FIB-4 score greater than 3.25
iii. F2 or F3 based a validated serum biomarker (i.e. FibroSure)
AND
4. An adequate trial and failure (6 months) of one of the following medications unless both are not tolerated or contraindicated:
i. Pioglitazone in patients with or without type 2 diabetes, OR
ii. Vitamin E (800 IU/day) in non-diabetic patients

Reauthorization Criteria:

Documentation of clinical benefit as evident by one of the following: Normalization of liver function tests (LFTs), improvement or no worsening in fibrosis, hepatocellular ballooning, lobular inflammation, or steatosis.

QUANTITY LIMIT:

5 mg tablet: 1 tablet per day
10 mg tablet: 1 tablet per day

ORAL ANTI-CANCER MEDICATIONS

MEDICATION(S)

ABIRATERONE ACETATE, AFINITOR, AFINITOR DISPERZ, ALECENSA, ALKERAN 2 MG TABLET, ALUNBRIG, AYVAKIT, BALVERSA, BEXAROTENE, BOSULIF, BRAFTOVI, BRUKINSA, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLEADA, ERLOTINIB HCL, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, FARYDAK, GILOTRIF, GLEEVEC, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA, INLYTA, INREBIC, IRESSA, JAKAFI, KISQALI, KISQALI FEMARA CO-PACK, LAPATINIB, LENVIMA, LONSURF, LORBRENA, LYNPARZA, MEKINIST, MEKTOVI, MELPHALAN, NERLYNX, NEXAVAR, NINLARO, NUBEQA, ODOMZO, PEMAZYRE, PIQRAY, POMALYST, REVLIMID, ROZLYTREK, RUBRACA, RYDAPT, SPRYCEL, STIVARGA, SUTENT, TAFINLAR, TAGRISSO, TALZENNA, TARCEVA, TARGRETIN, TASIGNA, TAZVERIK, TEMODAR 100 MG CAPSULE, TEMODAR 140 MG CAPSULE, TEMODAR 180 MG CAPSULE, TEMODAR 20 MG CAPSULE, TEMODAR 250 MG CAPSULE, TEMODAR 5 MG CAPSULE, TEMOZOLOMIDE, TIBSOVO, TRETINOIN 10 MG CAPSULE, TUKYSA, TURALIO, TYKERB, VANDETANIB, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VESANOID, VITRAKVI, VIZIMPRO, VOTRIENT, XALKORI, XOSPATA, XPOVIO, XTANDI, YONSA, ZEJULA, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA, ZYTIGA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation, with an oncologist.

COVERAGE DURATION

Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA

For initial authorization:

1. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

AND

2. For commercial members only, the following drug-specific criteria must be met:

a. For ribociclib (Kisqali®) for advanced or metastatic breast cancer: Documented trial, failure, intolerance or contraindication to palbociclib (Ibrance®) or abemaciclib (Verzenio®)

b. For talazoparib (Talzenna®) for recurrent or metastatic breast cancer: Documented trial, failure, intolerance or contraindication to olaparib (Lynparza®)

c. For niraparib (Zejula®) for recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer with a complete or partial response to platinum-based chemotherapy: Documented trial, failure, intolerance or contraindication to olaparib (Lynparza®) or rucaparib (Rubraca®)

For reauthorization: documentation of adequate response to the medication must be provided.

OSMOLEX ER

MEDICATION(S)
OSMOLEX ER

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Documentation of one of the following:
a. Diagnosis of Parkinson’s Disease
b. Diagnosis of drug-induced extrapyramidal symptoms
AND
2. Documented trial and failure of immediate release amantadine of a dose of at least 300 mg daily unless intolerable side effects at lower doses

QUANTITY LIMIT:

One tablet per day of Osmolex™ 129 mg, 193 mg and 258 mg tablets. Two tablets per day for 322 mg dosing kit

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist, psychiatrist, or expert in the treatment of movement disorders

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A

OTEZLA

MEDICATION(S)
OTEZLA

COVERED USES
N/A

EXCLUSION CRITERIA
When used in combination with other therapeutic immunomodulators (TIMs)

REQUIRED MEDICAL INFORMATION
1. For all requests, the patient must have an FDA labeled indication for the requested agent, or use to treat the indication is supported in drug compendia (i.e., American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics' DRUGDEX® System.)
AND
2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent (e.g., Humira®)
AND
3. One of the following:
a. For patients already established on apremilast (starting on samples will not be considered as established on therapy):
i. Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
b. Patients not established on the requested therapeutic immunomodulator must meet ALL of the following indication-specific criteria:

i. For Plaque Psoriasis:
1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol)

ii. For Psoriatic Arthritis:
1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)

iii. For active oral ulcers associated with Behcet's disease:
1. Patient has had at least three occurrences of active oral ulcers within the previous 12 months
2. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., corticosteroids)

Notes:
• An adequate trial and failure is defined as minimal to no symptom improvement after at least three (3) months of therapy.
• Conventional therapy requirements may be waived if the patient has previously used another therapeutic immunomodulator agent (e.g., Humira®) for the same indication
• Conventional therapy requirements may be waived with clinically appropriate medical rationale

QUANTITY LIMIT:

60 tablets per 30 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a rheumatologist or dermatologist

COVERAGE DURATION
Initial authorization will be approved for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A

OXERVATE

MEDICATION(S)
OXERVATE

COVERED USES
N/A

EXCLUSION CRITERIA
Retreatment of the same eye

REQUIRED MEDICAL INFORMATION
Documentation of which eye will be treated.
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an ophthalmologist

COVERAGE DURATION
Initial authorization will be approved for 8 weeks: an additional 8 weeks will be covered for treatment of the second eye when appropriate. Reauthorization will not be renewed for retreatment of the same eye.

OTHER CRITERIA
1. Patient has a diagnosis of stage 2 (recurrent/persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis in the affected eye(s) with diagnosis supported by chart notes
2. Patient is refractory to at least two conventional treatments for neurotrophic keratitis (e.g. preservative-free artificial tears, topical antibiotic eye drops, therapeutic contact lenses, amniotic membrane transplant, tarsorrhaphy)
3. The request specifies the affected eye(s) intended for treatment

QUANTITY LIMIT:
Cenegermin-bkbj ophthalmic solution 0.002% (Oxervate®): 1 ml (1 vial) per day (If both eyes are being treated a quantity of 2 mls (2 vials) a day will be allowed

OXYMORPHONE

MEDICATION(S)
OPANA, OXYMORPHONE HCL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of one of the following:
1. Documentation of active cancer pain OR
2. All of the following:
a. At least one non-opiate therapy such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (such as etodolac, diclofenac, meloxicam), or antidepressants/anticonvulsants for neuropathic pain (such as duloxetine, gabapentin, amitriptyline)
b. Trial and failure, contraindication or intolerance to immediate release morphine sulfate
c. Trial and failure, contraindication or intolerance to immediate release oxycodone
QUANTITY LIMITS:
For Commercial: Quantity Limits are based on 120 mg morphine equivalents per day dosing See Maximum Allowable Opioid Dose in Non-Malignant Chronic Pain policy (ORPTCANA31)
• Oxymorphone 5 mg: limited to 240 tablets per 30 days
• Oxymorphone 10 mg: limited to 120 tablets per 30 days
For Medicaid: Opioid doses greater than 90 mg Morphine Milligram Equivalent (MME) per day requires additional prior authorization. See Policy Maximum Allowable Opioid Dose (#ORPTCANA031) for clinical coverage criteria.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be for up to one year.

OTHER CRITERIA
N/A

PALYNZIQ

MEDICATION(S)
PALYNZIQ

COVERED USES
N/A

EXCLUSION CRITERIA
Used in combination with sapropterin (Kuvan®).

REQUIRED MEDICAL INFORMATION
Baseline blood Phe levels for initiation of therapy
Recent blood Phe levels are required for reauthorization

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for 18 years and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a metabolic disease specialist or a provider who specializes in the treatment of PKU.

COVERAGE DURATION
Initial authorization will be approved for 6 months, and reauthorization will be approved for 1 year.

OTHER CRITERIA
For initial authorization all of the following criteria must be met:
1. Diagnosis of phenylketonuria (PKU)
AND
2. Blood phenylalanine concentration more than 600 micromol/L despite management with dietary phenylalanine restriction and sapropterin (Kuvan®)

For Reauthorization:

One (1) of the following criteria must be met:
1. Documentation that blood phenylalanine concentration levels have decreased by at least 20% from

baseline and remain at least 20% below pretreatment baseline
OR
2. Documentation of a blood phenylalanine concentration less than or equal to 600 micromol/L
OR
3. For Initial Reauthorization Only: Documentation of plan for further up-titration to maximum dose of 40 mg once daily

Note:
If patient has been on pegvaliase 20 mg daily for at least 24 weeks and has not met the reauthorization criteria above, may consider approval for 6 months for trial of maximum dose of 40 mg once daily

QUANTITY LIMIT:

2.5 MG/0.5 ML: 8 syringes per 28 days
10 MG/0.5 ML: 1 syringe per day
20 MG/1 ML: 2 syringes per day

PCSK9 INHIBITORS

MEDICATION(S)
PRALUENT PEN, PRALUENT SYRINGE, REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use with another PCSK9 inhibitor

REQUIRED MEDICAL INFORMATION
Low-density lipoprotein cholesterol (LDL-C) levels, genetic testing results for familial hypercholesterolemia (FH) that may include the following genes: low-density lipoprotein cholesterol receptor gene (LDLR), familial defective apolipoprotein B gene (APOB), or pro-protein convertase subtilisin/kexin 9 gene (PCSK9)

For initiation of treatment, a prior authorization form is required and for continuation of therapy, ongoing attestation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For hyperlipidemia: must be prescribed by or in consultation with a cardiologist
For FH: must be prescribed by or in consultation with a cardiologist, endocrinologist, or board certified lipidologist

COVERAGE DURATION
Initial authorization for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
1. One of the following:
a. Provider attestation of a trial and failure of high-intensity statin therapy (e.g., atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily), defined as failure to achieve desired LDL-C lowering
OR
b. Provider attestation of an intolerance to TWO different statins, defined as inability to tolerate the lowest FDA approved starting dose
OR

c. The patient has an FDA labeled contraindication to a statin
2. Must meet listed criteria below for each specific diagnosis:
a. For familial hypercholesterolemia (FH), one of the following must be met:
i. A Dutch Lipid Clinic Network Criteria score of greater than or equal to 6 (see appendix)
OR
ii. Genetic mutation in one of the following genes: low-density lipoprotein receptors (LDLR), apolipoprotein B gene (APOB), or proprotein convertase subtilisin kexin type 9 (PCSK9), or ARH adaptor protein 1/LDLRAP1
OR
iii. LDL-C greater than 190 mg/dL (pretreatment or highest level while on treatment) and secondary causes have been ruled out. Secondary causes may include hypothyroidism, nephrosis, or extreme dietary patterns
b. For ASCVD, attestation of LDL-C greater than or equal to 70 mg/dL and history of clinical ASCVD, defined as one of the following:
i. Acute coronary syndromes
ii. History of myocardial infarction
iii. Stable/unstable angina
iv. Coronary or other arterial revascularization
v. Stroke or transient ischemic attack
vi. Peripheral artery disease presumed to be of atherosclerotic origin
vii. Clinically significant multi-vessel coronary heart disease presumed to be of atherosclerotic origin
3. For Praluent®:
a. Documented trial and failure, intolerance, or contraindication to evolocumab (Repatha®)

Initial Reauthorization: Provider attestation of response to therapy, defined as a decrease in LDL-C levels from pre-treatment levels.

QUANTITY LIMIT:

Two injections (2.0 mL) per 28 days

PEDIATRIC ANALGESICS

MEDICATION(S)

ACETAMINOPHEN-CODEINE, ASA-BUTALB-CAFFEINE-CODEINE, ASCOMP WITH CODEINE, BUTALB-ACETAMIN-CAF-COD 50-325, BUTALBITAL COMPOUND-CODEINE, CARISOPRODOL-ASPIRIN-CODEINE, CHERATUSSIN AC, CODEINE SULFATE, CODEINE-GUAIFENESIN, FIORINAL WITH CODEINE #3, G TUSSIN AC, GUAIATUSSIN AC, GUAIFENESIN AC, GUAIFENESIN DAC, GUAIFENESIN-CODEINE, LORTUSS EX, MAXI-TUSS AC, PROMETHAZINE-CODEINE, PROMETHAZINE-PHENYLEPH-CODEINE, ROBAFEN AC, TRAMADOL HCL 50 MG TABLET, TRAMADOL ER 100 MG TABLET, TRAMADOL ER 200 MG TABLET, TRAMADOL ER 300 MG TABLET, TRAMADOL HCL ER 100 MG TABLET, TRAMADOL HCL ER 200 MG TABLET, TRAMADOL HCL ER 300 MG TABLET, TRAMADOL HCL-ACETAMINOPHEN, TYLENOL-CODEINE NO.3, TYLENOL-CODEINE NO.4, ULTRACET, ULTRAM, ULTRAM ER, VIRTUSSIN AC, VIRTUSSIN DAC

COVERED USES

N/A

EXCLUSION CRITERIA

• Postoperative pain management following a tonsillectomy and/or adenoidectomy in children less than 18 years of age
• Use in children less than 12 years of age
• Use in children with history of obesity, sleep apnea, or severe lung disease

REQUIRED MEDICAL INFORMATION

1. Documented trial, failure, intolerance or contraindication to over-the-counter alternatives: acetaminophen and ibuprofen (when used for pain)
AND
2. A statement that the risk of use of codeine or tramadol for pediatric patients has been reviewed and the benefit of these medications for the pediatric member outweighs the risk

Reauthorization Criteria:

1. Documentation that the patient is responding well to therapy without side effects
AND
2. Documentation from the provider that continuation of therapy is medically necessary despite risks

QUANTITY LIMIT:

Tramadol ER formulations: limit of 1 tablet per 1 day
Ultram® 50 mg, tramadol 50mg: limit of 8 tablets per 1 day
Ultracet® 37.5-325 mg, tramadol/acetaminophen: limit of 10 tablets per 1 day

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 1 month

OTHER CRITERIA
N/A

PREVYMIS

MEDICATION(S)
PREVYMIS 240 MG TABLET, PREVYMIS 480 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for 18 years and older.

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a hematologist, oncologist, or Infectious Disease specialist.

COVERAGE DURATION
3 months, up to 100 days post-transplant

OTHER CRITERIA
ALL of the following must be met:
1) Member is within 100 days post- allogeneic transplant: AND
2) Cytomegalovirus (CMV) Recipient positive: AND
3) Member has ONE of the following:
a) Graft Versus Host Disease (GVHD) requiring greater than or equal to 1 mg/kg/day use of prednisone [or equivalent]
b) Receipt of lymphocyte depleting therapy (e.g. antithymocyte globulin [ATG], antithymocyte globulin equine [ATGAM], antithymocyte globulin rabbit [thymoglobulin], alemtuzumab, fludarabine) within the previous 6 months
c) Transplant was a cord blood allograft
d) History of CMV drug resistance within the past 6 months
4) If IV letermovir is being requested, rationale for not using oral formulation must be provided (e.g. patient is unable to swallow)

PROCYSBI

MEDICATION(S)
PROCYSBI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
1 year of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
All of the following:
1. Confirmed diagnosis of nephropathic cystinosis as evidenced by measuring leukocyte cystine levels (LCL) or genetic analysis of the CTNS gene (gene that encodes cystinosin)
2. Documentation of trial and failure, contraindication or intolerance to Cystagon® immediate release cysteamine capsules.

PROMACTA

MEDICATION(S)
PROMACTA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Platelet Count

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist, hematologist, or hepatologist.

COVERAGE DURATION
Initial authorization will be approved for 4 months. Reauthorization will be approved for 6 months

OTHER CRITERIA
Chronic immune thrombocytopenia (ITP):

1. Patient is at risk for bleeding with a platelet count of less than 30 x 10 to the 9th power per liter.
AND
2. Treatment by at least one of the following was ineffective or not tolerated:
a. Systemic corticosteroids,
OR
b. Immune globulin,
OR
c. Splenectomy

Severe aplastic anemia:

1. Patient is at risk for bleeding with a platelet count of less than 30 x 10 to the 9th power per liter.

For Reauthorization for ITP or severe aplastic anemia:

Platelet levels demonstrating response to therapy as well as documentation that eltrombopag continues to be required to maintain a platelet count of at least 50 x 10 to the 9th power per liter.

PULMONARY ARTERIAL HYPERTENSION

MEDICATION(S)

ADCIRCA, ADEMPAS, ALYQ, AMBRISENTAN, BOSENTAN, LETAIRIS, OPSUMIT, REVATIO 10 MG/ML ORAL SUSP, SILDENAFIL 10 MG/ML ORAL SUSP, TADALAFIL 20 MG TABLET, TRACLEER, TYVASO, TYVASO INSTITUTIONAL START KIT, TYVASO REFILL KIT, TYVASO STARTER KIT, UPTRAVI

COVERED USES

N/A

EXCLUSION CRITERIA

• Heart failure caused by reduced left ventricular ejection fraction for epoprostenol (Flolan®, Veletri®)
• Idiopathic interstitial pneumonia for riociguat (Adempas®) only

REQUIRED MEDICAL INFORMATION

For initiation of single or dual therapy, a prior authorization form and relevant chart notes documenting medical rationale are required: and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a pulmonologist or cardiologist

COVERAGE DURATION

Initial authorization for 12 months. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA

For initial authorization the following criteria must be documented:
1. Diagnosis of Pulmonary Arterial Hypertension (PAH) confirmed by right heart catheterization as defined by:
A. Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest
AND
B. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHg
AND
C. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU)
AND

2. Patient has documented World Health Organization (WHO) Group 1 classification PAH(or WHO Group 4 classification CTEPH for Adempas® only) with WHO/New York Heart Association (NYHA) functional class as outlined below:
A. Flolan®, Veletri®, and Ventavis: Class III or IV
B. Tyvaso®: Class III or IV
C. All other therapies: Class II, III, or IV
AND
3. For sildenafil citrate oral suspension or parenteralinjection (Revatio®): Documentation of trial and failure, intolerance, or contraindication to generic sildenafil citrate tablets (Revatio®)

Reauthorization:

Documentation of response to therapy including lack of disease progression, improvement in WHO functional class,

QUANTITY LIMIT:

• Selexipag (Uptravi®): 2 tablets/day -A one-time fill will be allowed for the Uptravi® Titration pack for initial dose titration
• Sildenafil (Revatio®): 3 tablets/day
• Tadalafil (Adcirca®): 2 tablets/day

QBREXZA

MEDICATION(S)
QBREXZA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for 9 years old and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
Initial authorization:
1. Diagnosis of severe primary axillary hyperhidrosis
2. Documentation that patient has had axillary hyperhidrosis for at least 6 months
3. Documentation that member's hyperhidrosis is causing social anxiety, depression, or other issues that are impacting quality of life
4. Documented trial and failure of Drysol® for a least 1 month, unless contraindicated or clinically significant adverse effects were experienced
5. For Age 18 years or older only: Documented trial and failure of botulinum toxin for at least 6 months, unless contraindicated or clinically significant adverse effects were experienced

QUANTITY LIMIT:
Qbrexza® (glycopyrronium tosylate 2.4% towelette): 1 towelette per day
*Qbrexza® is applied once daily and the same towelette should be used for each arm

QUDEXY XR, TROKENDI XR

MEDICATION(S)
QUDEXY XR, TOPIRAMATE ER

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For seizure disorders, one of the following must be met:
1. The patient is currently established on therapy with the requested medication (Note: starting on samples will not be considered established on therapy)
OR
2. Documentation of trial and failure, intolerance or contraindication to topiramate immediate release AND one additional formulary anti-epileptic medication: e.g. valproic acid, clonazepam or lamotrigine.
OR
3. Prescriber is a neurologist.

For migraine prophylaxis all of the following criteria must be met:
1. Must be prescribed by, or in consultation with, a neurologist
2. Documented trial and failure, intolerance or contraindication to immediate release topiramate
3. Documentation of trial and failure, intolerance, or contraindication to at least one prophylactic medication from at least three (3) of the following categories:
a. Anticonvulsants other than topiramate (e.g., divalproex, valproate)
b. Beta-blockers (e.g., metoprolol, propranolol, timolol)
c. Antidepressants (e.g., amitriptyline, venlafaxine)
d. Botulinum toxin
e. CGRP antagonist [e.g, erenumab (Aimovig®) or galcanezumab(Emgality®)]

An adequate trial and failure is defined as minimal to no improvement after at least three (3) months of therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA

N/A

REGRANEX

MEDICATION(S)
REGRANEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and one reauthorization will be approved for 90 days.

OTHER CRITERIA
For initiation, must submit the following:
1. Documentation of adequate blood tissue supply to the affected area.
AND
2. The record must demonstrate use of good ulcer care for a minimum of 8 weeks prior to request for initiation of therapy. Good ulcer care will generally include documentation of the following:
a. Establishment of adequate blood supply as indicated above
b. Determination of adequate nutritional status with a serum albumin level of greater than 2g/dL
c. Appropriate debridement to remove dead tissue with ongoing debridement as necessary
d. No weight on affected area to relieve pressure points
e. Systemic treatment of wound infections, if present
f. Maintenance of a moist wound environment (dressing changes including alginates, foams, hydrocolloids, hydro gels, and transparent films).

For reauthorization for a second 90 day course, must submit documentation showing an adequate

response defined by a 30% reduction or greater in ulcer size.

There is no medical evidence to justify ongoing treatment after 180 days of Regranex® treatment.

RESCUE MEDICATIONS FOR EPILEPSY

MEDICATION(S)
NAYZILAM, VALTOCO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For patients 18 years of age and older only: Documented trial, failure, intolerance or contraindication to clonazepam oral disintegrating tablets or documentation of why therapy would not be appropriate for member

QUANTITY LIMIT:

2 doses or 1 package per month

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
N/A

REVCOVI

MEDICATION(S)
REVCOVI

COVERED USES
N/A

EXCLUSION CRITERIA
Other forms of autosomal recessive severe combined immune deficiencies

REQUIRED MEDICAL INFORMATION
Initial authorization will require:
• A current (within 6 months) patient weight & patient height
• Platelet count
• ADA gene mutation or ADA catalytic activity level
• Metabolite deoxyadenosine triphosphate (dATP) or total dAdo nucleotides level

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

Reauthorization will require:

Plasma target trough ADA activity level & trough erythrocyte dAXP level.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an expert in the treatment of immune deficiencies (e.g. immunologist, hematologist)

COVERAGE DURATION
Initial authorization will be approved for four (4) months
Reauthorization will be approved for six (6) months

OTHER CRITERIA
1. Diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by one (1) of the following:

• Documentation of a mutation in the ADA gene by molecular genetic testing
• Deficient ADA catalytic activity (less than 1% of normal) in hemolysates (in untransfused individuals) or in extracts of other cells (e.g., blood mononuclear cells, fibroblasts)
AND
2. A marked increase in the metabolite deoxyadenosine triphosphate (dATP) or total dAdo nucleotides [the sum of deoxyadenosine monophosphate (dAMP), deoxyadenosine diphosphate (dADP), and dATP] in erythrocytes
AND
3. Documentation showing that patient is not a candidate for or has failed a hematopoietic stem cell transplantation (HSCT)
a) May be approved as a “bridge” therapy before undergoing HSCT or a HSC-Gene Therapy clinical trial if a donor/ clinical trial has been identified (subject to policy coverage durations)
AND
4. Documentation that patient does not have severe thrombocytopenia (platelet count less than 50 x 109/L)
AND
5. Documentation of patient’s recent weight and that dosing is within FDA labeled dosing

Reauthorization criteria:

1. Documentation of plasma target trough ADA activity of at least 30 mmol/hr/L in the past two (2) months
AND
2. Documentation of a trough erythrocyte dAXP level maintained below 0.02 mmol/L in the past six (6) months
AND
3. Documentation of immune function improvement (e.g. decrease in number of infections)
AND
4. Documentation of patient’s recent weight and that dosing is within FDA labeled dosing

SABRIL

MEDICATION(S)
SABRIL, VIGABATRIN, VIGADRONE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For refractory complex partial seizures:
1. Must be at least 2 years of age
AND
2. Documentation of trial and failure, contraindication, or intolerance to 2 alternative formulary generic antiepileptic medications

For infantile spasms:
1. Must be between 1 month and 2 years of age

AGE RESTRICTION
For complex partial seizures: approved for ages 2 years and older.

For infantile spasms: approved for ages 1 month to 2 years old.

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist.

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A

SANDOSTATIN / SANDOSTATIN LAR

MEDICATION(S)
OCTREOTIDE ACETATE, SANDOSTATIN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Acromegaly:
Initial authorization

1. Confirmed diagnosis of acromegaly
2. Documentation of an inadequate response to surgery or pituitary irradiation or patient is not a candidate for surgical resection and pituitary irradiation
3. History of failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses
4. For Sandostatin LAR, patient has had a trial of short-acting octreotide and responded to and tolerated therapy

Re-authorization:

1. Documentation of a positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)

Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing:
Initial authorization

1. Documentation that patient has severe diarrhea or flushing caused by a carcinoid tumor
2. For Sandostatin LAR, patient has had a trial of short-acting octreotide and responded to and tolerated therapy

Re-authorization:

1. Documentation of an improvement in the number of diarrhea and flushing episodes

Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea:
Initial authorization

1. Documentation that patient has severe diarrhea caused by a vasoactive intestinal peptide tumors
2. For Sandostatin LAR, patient has had a trial of short-acting octreotide and responded to and tolerated therapy

Re-authorization:

1. Documentation of an improvement in the number of diarrhea episodes

For chemotherapy induced diarrhea:
Initial authorization

1. Documentation that patient has severe diarrhea caused by chemotherapy
2. Documentation of an inadequate response or contraindication to loperamide
3. For Sandostatin LAR, patient has had a trial of short-acting octreotide and responded to and tolerated therapy

Re-authorization:

1. Documentation of an improvement in the number of diarrhea episodes

For AIDS-related diarrhea:
Initial authorization

1. Documentation that patient has severe diarrhea
2. Documentation of an inadequate response or contraindication to loperamide and diphenoxylate (Lomotil®)
3. For Sandostatin LAR, patient has had a trial of short-acting octreotide and responded to and tolerated therapy

Re-authorization:

1. Documentation of an improvement in the number of diarrhea episodes

For variceal bleeding:

1. Documentation of variceal bleeding
2. Documentation that therapy will be used short term (less than 1 month)

Note:
Short-term treatment of acute bleeding of gastroesophageal varicies will be covered for one month of therapy only. Use beyond one month is not considered medically necessary

For oncologic diagnoses:
For initial authorization:

Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

AGE RESTRICTION
Safety and efficacy has not been established in the pediatric population

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Variceal bleeding: One (1) month
Other indications: Initial authorization and reauthorization for 12 months

OTHER CRITERIA
N/A

SAVELLA

MEDICATION(S)
SAVELLA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of an adequate trial and failure*, intolerance, or contraindication to the following:
1. Gabapentin OR pregabalin (Lyrica®)
AND
2. One of the following:
a. A Selective serotonin reuptake inhibitors/Serotonin-norepinephrine reuptake inhibitors (SSRI)/(SNRI) (e.g. fluoxetine, duloxetine)
b. A tricyclic antidepressant (TCA) medication (e.g., amitriptyline)

*An adequate trial and failure is defined as adherence to at least 6 weeks of therapy without improvement in symptoms

QUANTITY LIMITS:
One pack (55 tablets) per 28 days for the Titration Pack.
Sixty capsules per 30 days for the 12.5mg, 25mg, 50mg and 100mg tablet strengths.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
N/A

SIGNIFOR

MEDICATION(S)
SIGNIFOR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Diagnosis of endogenous Cushing’s Disease
AND
2. Documentation of one of the following:
a. Patient has failed pituitary surgery or
b. Patient is not a candidate for surgery

Reauthorization:

1. Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
Initial authorization will be approved for three months and reauthorization will be approved for one year

OTHER CRITERIA
N/A

SOMAVERT

MEDICATION(S)
SOMAVERT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
1. Diagnosis of acromegaly
AND
2. Documentation of inaquate response or that member is not a candidate for one of the following treatment options:
a. Surgery
b. Radiation therapy
c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy
AND
3. Documentation of trial and failure, intolerance or contraindication to octreotide injection therapy

Reauthorization requires documentation of a positive response to therapy, such as a decrease or normalization of insulin like growth factor (IGF)-1

STRENSIQ

MEDICATION(S)
STRENSIQ

COVERED USES
N/A

EXCLUSION CRITERIA
Adult-onset hypophosphatasia or odonto-hypophosphatasia

REQUIRED MEDICAL INFORMATION
Total serum alkaline phosphatase (ALP), current patient weight
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for 6 months.

OTHER CRITERIA
Initial Authorization:
Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia (HPP) confirmed by ALL of the following criteria:
1. Documentation of one of the following:
a. Confirmation of at least one pathogenic variant in tissue-nonspecific alkaline phosphatase (TNALPL or ALPL) gene mutation:
OR
b. Total serum alkaline phosphatase (ALP) below the lower limit of normal for age AND Plasma pyridoxal-5'-phosphate (PLP) above the upper limit.

Note: Plasma PLP should not be measured while the member is receiving pyridoxine treatment

2. Documentation of least one of the following HPP related symptoms prior to the age of 18:

a. Vitamin B6-dependent seizures
b. Respiratory insufficiency
c. Hypotonia, myopathy, gross motor delay
d. Low trauma or non-traumatic fractures
e. Premature loss of deciduous teeth, carious teeth, or abnormal dentition
f. Gait disturbance such as delayed walking or waddling gait
g. Osteopenia, osteoporosis, or low bone mineral content for age attributable to hypophosphatasia
h. Hypercalcemia, hypercalciuria, nephrocalcinosis
3. Documentation of at least one of the following radiographic features prior to the age of 18:
a. Knock Knees
b. Rachitic chest
c. Bowing of leg(s)
d. Craniosynostosis
e. Infantile rickets
f. Osteochondral spurs
4. For members 18 years of age or older at the time of request, in addition to criteria 1-3 above, documentation is required of medical history consistent with progressive, untreated disease, demonstrating all of the following
i. Limited mobility or functional capacity
ii. Long term chronic musculoskeletal pain
iii. Current radiographic evidence of widespread skeletal demineralization, pseudofractures, and skeletal deformities due to recurrent fractures and/or widened metaphyseal

Reauthorization:

Pediatric patients: Documentation of response to therapy with improvements in at least one of the following: respiratory status, bone mineralization, or mobility

Adult patients: Documentation of response to therapy with all of the following: increased mobility, decreased pain, and evidence of improved bone mineralization

QUANTITY LIMITS:

Initial dose approval will be based on patient's current weight (appendix 2). Changes in dose will require new authorization with updated patient's weight and relevant chart notes.

SUBLINGUAL IMMUNOTHERAPY WITH ALLERGEN-SPECIFIC POLLEN EXTRACTS (SLIT)

MEDICATION(S)
GRASTEK, ODACTRA, ORALAIR, RAGWITEK

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
These allergen extracts must be prescribed by or in consultation with an Allergist, an Immunologist, an Otolaryngologist, or other physician currently providing subcutaneous immunotherapy to patients in their practice.

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
For treatment with sublingual immunotherapy, patients must meet all the following for initial authorization:
1. Diagnosis of allergic rhinitis, with or without conjunctivitis
AND
2. Documentation that member remains symptomatic despite treatment with both of the following:
a) An intranasal steroid
b) An oral anti-histamine
AND
3. Documentation that the sublingual immunotherapy will begin at least 12 weeks (for Grastek® or Ragwitek®) or 14 weeks (for Oralair®) before the start of the allergy season
AND

4. Documentation of a positive skin test or pollen specific antibodies to the relevant allergen:
a) Grastek: Timothy grass or cross-reactive grass
b) Oralair: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass
c) Ragwitek: Short Ragweed
d) Odactra: House dust mite
AND
5. Subcutaneous immunotherapy will not be used concurrently

For reauthorization:

Consistent use during treatment period for allergy season previously approved for coverage

For coverage by Medicaid members:
Sublingual immunotherapy treatment requires prior authorization for Medicaid members and is approvable only when allergic rhinitis impacts another condition designated as a covered line item by the Oregon Health Services Commission (i.e. an above the line diagnosis).

Additional Criteria for Medicaid members include:
1. Confirmed diagnosis of one of the following co-morbidities:
a. Asthma or reactive airway within the past year
b. Chronic sinusitis
c. Acute sinusitis
d. Sleep apnea

SUCRAID

MEDICATION(S)
SUCRAID

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of secondary (acquired) disaccharide deficiencies

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
Initial authorization will be approved for 6 months and reauthorization will be approved for 1 year

OTHER CRITERIA
Initial authorization:
1. Diagnosis of congenital sucrose-isomaltase deficiency has been confirmed by one of the following:
a. A small bowel biopsy with disaccharidase enzyme assay that is positive for sucrase deficiency [i.e., a sucrase level below the laboratory's reference level, typically less than 25 mcM/min/g]
b. A positive genetic test for a pathogenetic mutation in the sucrose-isomaltose (SI) gene
c. If small bowel biopsy is clinically inappropriate, difficult, or inconvenient to perform, then the patient must meet all the following:
i. Stool pH less than 6
ii. A negative lactose breath test
iii. Breath hydrogen increase greater than 10 ppm following fasting sucrose challenge
2. Documentation that patient is having significant symptoms due to congenital sucrose-isomaltase deficiency such as diarrhea, bloating, abdominal cramping, failure to thrive, dehydration and malnutrition
3. Documentation that patient has tried and failed a low sucrose and starch diet
4. Documentation that sacrosidase therapy will be used in conjunction with dietary limitation of sucrose and

starch intake

Reauthorization criteria:

1. Documentation of a positive improvement in gastrointestinal symptoms
2. Documentation that sacrosidase therapy will be used continue to be given in conjunction with dietary limitation of sucrose and starch intake

SYMLINPEN

MEDICATION(S)
SYMLINPEN 120, SYMLINPEN 60

COVERED USES
N/A

EXCLUSION CRITERIA
Patients that require the use of drugs known to alter gastrointestinal motility (i.e. GI anticholinergics, metoclopramide)
Patients with a confirmed diagnosis of gastroparesis

REQUIRED MEDICAL INFORMATION
HbA1c
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an endocrinologist or credentialed diabetic specialist.

COVERAGE DURATION
Initial authorization for 6 months and reauthorization will be approved for 1 year subject to effective response criteria.

OTHER CRITERIA
Initial Authorization:
All of the following criteria must be met:
1. Patient is an insulin dependent diabetic AND
2. Patient's HbA1c is greater than or equal to 7% and is less than or equal to 9% AND
3. Documentation of the failure of achieving glycemic control despite multiple titrations and adjustments with various basal and bolus insulin dosing regimens

Reauthorization: HbA1c remains less than or equal to 9%.

SYMPAZAN

MEDICATION(S)
SYMPAZAN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
1. The patient is currently established on therapy with the requested medication (Note: starting on samples will not be considered established on therapy)
OR
2. Documentation of one of the following:
a. Trial and failure of clobazam tablets or suspension OR
b. Contraindication or intolerance to both clobazam tablets and suspension
AND
3. Documentation of trial and failure, contraindication, or intolerance to two (2) other alternative generic formulary agents (i.e. valproic acid, lamotrigine, topiramate, felbamate)

SYPRINE

MEDICATION(S)
CLOVIQUE, SYPRINE, TRIENTINE HCL

COVERED USES
N/A

EXCLUSION CRITERIA
Cystinuria or rheumatoid arthritis

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or genetic specialist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
Documentation of severe or intolerable adverse effects to penicillamine (Depen®)

TAFAMIDIS

MEDICATION(S)
VYNDAMAX, VYNDAQEL

COVERED USES
N/A

EXCLUSION CRITERIA
1. A New York Heart Association (NYHA) Heart Failure classification of IV
2. Prior liver transplantation
3. Implanted cardiac mechanical assist device (e.g. left ventricular assist device (LVAD)
4. Used in combination with other therapies for the treatment of transthyretin-mediated amyloidosis (e.g. patisiran, inotersen)

REQUIRED MEDICAL INFORMATION
New York Heart Association (NYHA) Heart Failure classification, results of genetic testing

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Must be written by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
Initial authorization:
1. Documentation of genetic testing results for mutations of the transthyretin (TTR) gene (patient may have a genetic variation or be wild type)
2. Confirmation of amyloid deposits showing cardiac involvement by ONE of the following:
a. A positive 99mTechnetium-Pyrophosphate (99mTc-PYP) scan
b. A positive cardiac biopsy for ATTR amyloid
c. A positive non-cardiac biopsy for ATTR amyloid and evidence of cardiac involvement by evidence of

cardiac involvement by end-diastolic interventricular septal wall thickness greater than 12 mm (by echocardiogram or MRI) or suggestive cardiac MRI findings
3. Documentation of patient's NYHA functional class (functional class IV is excluded from coverage)
4. Documentation of clinical signs or symptoms of cardiomyopathy and/or heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema, elevated BNP or NT-BNP levels)
5. Documentation of baseline 6-minute walk test or Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS)

Reauthorization:

1. Documentation of a positive clinical response by at least one of the following:
a. Evidence of slowing of clinical decline
b. Reduced number of cardiovascular hospitalizations
c. Improvement or stabilization of the 6-minute walk test
d. Improvement or stabilization in the KCCQ-OS

QUANTITY LIMIT:

Tafamidis meglumine capsule (Vyndaqel®): 4 capsules per day
Tafamidis capsule (Vydamax®): 1 capsule per day

THERAPEUTIC IMMUNOMODULATORS (TIMS)

MEDICATION(S)

ACTEMRA 162 MG/0.9 ML SYRINGE, ACTEMRA ACTPEN, CIMZIA 2X200 MG/ML SYRINGE KIT, CIMZIA 2X200 MG/ML(X3)START KT, COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE, ENBREL, ENBREL MINI, ENBREL SURECLICK, HUMIRA, HUMIRA PEDIATRIC CROHN'S, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS, HUMIRA PEN PSOR-UVEITS-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN'S, HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PSOR-UV-ADOL HS, KINERET, ORENCIA 125 MG/ML SYRINGE, ORENCIA 50 MG/0.4 ML SYRINGE, ORENCIA 87.5 MG/0.7 ML SYRINGE, ORENCIA CLICKJECT, RINVOQ, SKYRIZI (2 SYRINGES) KIT, STELARA 45 MG/0.5 ML SYRINGE, STELARA 90 MG/ML SYRINGE, TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE, TREMFYA, XELJANZ, XELJANZ XR

COVERED USES

N/A

EXCLUSION CRITERIA

Combination therapy with another therapeutic immunomodulator (TIM) agent or Otezla®

REQUIRED MEDICAL INFORMATION

1. For all requests, the patient must have an FDA labeled indication for the requested agent, or use to treat the indication is supported in drug compendia (i.e., American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics' DRUGDEX® System.)
AND
2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent or apremilast (Otezla®)
AND
3. One of the following:
a. For patients already established on the requested therapeutic immunomodulator (starting on samples will not be considered as established on therapy):
i. Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
b. Patients not established on the requested therapeutic immunomodulator must meet ALL of the following indication-specific criteria:
i. For moderate to severe Ulcerative Colitis:
1. For non-preferred TIMs therapies: documentation of trial, failure?, intolerance, or contraindication to both adalimumab (Humira®) and ustekinumab (Stelara®)
ii. For moderate to severe non-fistulizing Crohn's Disease:

1. For non-preferred TIMs therapies:
a. Documentation of trial, failure?, intolerance, or contraindication to both adalimumab (Humira®) and ustekinumab (Stelara®)
AND
b. If patient has satisfied criteria above (ii.1.a.), documentation of trial and failure?, intolerance, or contraindication to certolizumab (Cimzia®)
i. For Rheumatoid Arthritis:
1. Documentation of trial and failure?, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
2. For non-preferred TIMs therapies:
a. Documentation of trial and failure?, intolerance, or contraindication to two of the following agents:
i. etanercept (Enbrel®)
ii. adalimumab (Humira®)
iii. upadacitinib (Rinvoq®)
AND
b. If patient has satisfied criteria above (iii.2.a.), documentation of trial and failure?, intolerance, or contraindication to tocilizumab (Actemra®) or certolizumab (Cimzia®)
ii. For Juvenile Idiopathic Arthritis:
1. Documentation of trial and failure?, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
2. For non-preferred TIMs therapies:
a. Documentation of trial and failure?, intolerance, or contraindication to both etanercept (Enbrel®) and adalimumab (Humira®)
AND
b. If patient has satisfied criteria above (ii.2.a.), documentation of trial and failure?, intolerance, or contraindication to tocilizumab (Actemra®)
iii. For moderate to severe Plaque Psoriasis:
1. Documentation of trial and failure?, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol)
2. For non-preferred TIMs therapies:
a. Documentation of trial and failure?, intolerance, or contraindication to three of the following preferred agents:
i. etanercept (Enbrel®)
ii. adalimumab (Humira®)
iii. secukinumab (Cosentyx®)
iv. ustekinumab (Stelara®)
v. gulselkumab (Tremfya®)
vi. risankizumab-rzaa (Skyrizi®)
AND
b. If patient has satisfied criteria above (iii.2.a.), documentation of trial and failure?, intolerance, or

contraindication to certolizumab (Cimzia®)
vii. For Psoriatic Arthritis:
1. Documentation of trial and failure?, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
2. For non-preferred TIMs therapies:
a. Documentation of trial and failure?, intolerance, or contraindication to two of the following preferred agents:
i. etanercept (Enbrel®)
ii. adalimumab (Humira®)
iii. secukinumab (Cosentyx®)
iv. ustekinumab (Stelara®)
AND
b. If patient has satisfied criteria above (vii.2.a.), documentation of trial and failure?, intolerance, or contraindication to certolizumab (Cimzia®)
viii. For Ankylosing Spondylitis:
1. For non-preferred TIMs therapies:
a. Documentation of trial and failure?, intolerance, or contraindication to three of the following preferred agents:
i. etanercept (Enbrel®)
ii. adalimumab (Humira®)
iii. secukinumab (Cosentyx®)
AND
b. If patient has satisfied criteria above (viii.2.a.), documentation of trial and failure?, intolerance, or contraindication to certolizumab (Cimzia®)
viii. For uveitis or Hidradenitis Suppurativa:
1. For non-preferred TIMs therapies: documentation of trial and failure?, intolerance, or contraindication to adalimumab (Humira®)
ix. For giant cell arteritis:
1. Documentation of trial and failure?, intolerance, or contraindication to at least one conventional therapy (e.g., Systemic corticosteroid therapy)
x. For Non-radiographic axial spondyloarthritis: certolizumab (Cimzia®) may be covered

*An adequate trial and failure is defined as minimal to no symptom improvement after at least three (3) months of therapy.

Notes:
• Conventional therapy requirements may be waived if the patient has previously used another therapeutic immunomodulator agent OR apremilast (Otezla®) for the same indication*
• Conventional therapy and preferred agent requirements may be waived with clinically appropriate medical rationale

*apremilast is FDA approved for psoriasis and psoriatic arthritis

For quantity limit exception requests (See Appendix 1 for specific quantity limits). Note exceptions below
1. For patients already established on the requested dose and frequency
a. Documentation of response to therapy with increased dosing
AND
b. Documentation of attempt to taper to FDA labeled dosing and return of significant symptoms OR medical rationale is provided for maintaining current dosing regimen without a taper attempt
2. For patients not established on requested dose and frequency (e.g., requesting dose escalation), all of the following criteria must be met:
a. Dose requested is ONLY for increased dose or increased frequency (changes in both dose and frequency at the same time will not be approved)
b. Documented inadequate response to the medication after at least six (6) months of therapy at the FDA labeled dosing
c. Documentation has been submitted in support of therapy with a higher dose for the intended diagnosis (e.g., high-quality peer reviewed literature, guidelines, other clinical information)
d. For RA only, documentation of inadequate response to concomitant therapy with systemic disease modifying anti-rheumatic (DMARD) therapy (e.g., methotrexate, leflunomide, sulfasalazine) for at least six (6), or there is a contraindication to their use

Exceptions
1. For Hidradenitis Suppurativa: once weekly dosing of Humira® will be approved
2. For Crohn's Disease and Ulcerative Colitis, Stelara® may be approved for FDA labeled dosing for this condition (90 mg every 8 weeks)

QUANTITY LIMITS: See Appendix 1

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
• Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis: must be prescribed by, or in consultation with, a rheumatologist
• Psoriasis: must be prescribed by, or in consultation with, a dermatologist
• Psoriatic arthritis: must be prescribed by, or in consultation with, a dermatologist or rheumatologist
• Inflammatory Bowel Disease: must be prescribed by, or in consultation with, a gastroenterologist

COVERAGE DURATION
• Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

• Quantity Limitation: Initial authorization will be approved for six (6) months and reauthorization will be approved for one (1) year.
o Exception: Authorization for once weekly dosing of adalimumab (Humira®) for Hidradenitis Suppurativa or Crohn’s disease and every 8 week dosing of ustekinumab (Stelara®) for Crohn’s disease and Ulcerative Colitis may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
N/A

THIOLA

MEDICATION(S)
THIOLA, THIOLA EC

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
24-hour urine collection with urinary cysteine levels
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a Nephrologist or Urologist.

COVERAGE DURATION
Initial authorization will be approved for 6 months and reauthorization will be approved for one year.

OTHER CRITERIA
All of the following criteria must be met:
1. Confirmation of cystinuria by at least one 24-hour urine collection with measurement of urinary cysteine levels greater than 500 mg/day
2. Documented of failure to conservative treatment with increased fluid intake (at least 2.5 liters/day), a diet restricted in sodium and protein, and urine alkalization with potassium citrate (to achieve pH greater than 7). Failure is defined by:
a. Failure to lower the urine cysteine concentration to below 243 mg/L and to raise the urine pH to above 7 in a 24 urine (or, if available, failure to lower the urinary supersaturation of cysteine to below 1)
b. Persistence of cysteine crystals visualized by urinalysis

Reauthorization requires documentation of urine cysteine concentration less than 300 mg/L or reduction in production of cysteine stones.

TOLVAPTAN

MEDICATION(S)
JYNARQUE, SAMSCA, TOLVAPTAN

COVERED USES
N/A

EXCLUSION CRITERIA
• Hepatic Impairment
• Anuria
• Hypovolemia
• For Jynarque®: Patients with eGFR of less than 25 mL/min

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
May be covered for patients aged 18 years and older.

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a nephrologist.

COVERAGE DURATION
Jynarque®: Initial approval and reauthorization will be approved for one year
Samsca®: Authorization will be approved for 30 days.

OTHER CRITERIA
For autosomal dominant polycystic kidney disease (ADPKD), Jynarque® may be approved when all of the following criteria are met:
1. Diagnosis of ADPKD confirmed by modified Pei-Ravine criteria:
a. With family history: several cysts per kidney (3 if by sonography, 5 if by computed tomography or magnetic resonance imaging)
b. Without family history: 10 cysts per kidney (by any radiologic method above) and exclusion of other cystic kidney diseases.
i. Conditions to be excluded include: multiple simple renal cysts, renal tubular acidosis, cystic dysplasia of the kidney, multicystic kidney, multilocular cysts of the kidney, medullary cystic kidney and acquired cystic disease of the kidney

2. The patient must have a confirmed diagnois of rapidly progressing ADPKD by at least one of the following criteria:
a. eGFR decline of at least 5 mL/min/1.73 m2 per year over 1 year
b. eGFR decline of at least 2.5 mL/min/1.73 m2 per year over a period of 5 years
c. Total kidney volume increase of at least 5% per year confirmed by at least 3 repeated ultrasound or MRI measurements taken at least 6 months apart
3. Patient does not have significant renal disease other than ADPKD (e.g., renal cancer, acute kidney injury)

Reauthorization:

1. Documentation of a positive response to therapy (such as a slowing in patient's decline in kidney function)

For hypervolemic and euvolemic hyponatremia, Samsca® may be covered when all of the following criteria are met:
1. One of the following:
a. Serum sodium of less than 125 mEq/L
b. Less marked hyponatremia (less than 135 mEq/L), but symptomatic
2. Evidence that initiation and re-initiation of therapy in a hospital setting where serum sodium can be monitored closely
3. Patient does not have any of the following: Urgent need to raise serum sodium acutely (e.g., acute/transient hyponatremia associated with head trauma)

TOPICAL ANTIBIOTICS

MEDICATION(S)
ALTABAX, XEPI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one month

OTHER CRITERIA
Documented trial and failure, intolerance or contraindication to mupirocin 2% ointment

TRANSTHYRETIN (TTR) LOWERING AGENTS

MEDICATION(S)
TEGSEDI

COVERED USES
N/A

EXCLUSION CRITERIA
• New York Heart Association (NYHA) Heart Functional class III or IV
• Hereditary transthyretin-medicated amyloidosis with cardiomyopathy
• Others forms of amyloidosis that is not due to a genetic mutation in the TTR gene
• Patients without the presence of polyneuropathy symptoms associated with hATTR amyloidosis
• Patients with type I or type II diabetes
• Previous organ transplant(s) requiring immunosuppression
• Malignancy within the past five years
• Uncontrolled cardiac arrhythmia or unstable angina

REQUIRED MEDICAL INFORMATION
• Genetic test results (TTR gene testing documenting mutation)
• Documentation of baseline polyneuropathy and impairment demonstrated by the following three (3) standardized tools:
1. Polyneuropathy disability (PND) score OR familial amyloid polyneuropathy (FAP) stage
2. Neuropathy impairment score (NIS)
3. Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of amyloidosis

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months

OTHER CRITERIA

1. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
AND
2. Documentation of a pathogenic TTR mutation
AND
3. Patient has a baseline polyneuropathy disability (PND) score of less or equal to IIIB OR has a baseline familial amyloid polyneuropathy (FAP) stage of I or II
AND
4. Baseline neuropathy impairment score (NIS) between 5 and 130
AND
5. Baseline Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score
AND
6. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two of the following:
• Peripheral sensorimotor polyneuropathy (e.g., tingling or increased pain in the hands, feet, hands and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)
• Autonomic neuropathy symptoms (e.g., orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety])
AND
7. For patisiran (Onpattro®): Not taking in combination with inotersen (Tegsedi®) or tafamidis
OR
For inotersen (Tegsedi®): Not taking in combination with patisiran (Onpattro®) or tafamidis

Reauthorization:
1. Documentation that patient is tolerating applicable gene therapy (i.e. inotersen (Tegsedi®) or patisiran (Onpattro®))
AND
2. Documented improvement or stabilization in polyneuropathy symptoms, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) AND at least one of the following measures:
a) Baseline polyneuropathy disability (PND) score
b) Familial amyloid polyneuropathy (FAP) stage
c) Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score

QUANTITY LIMIT:
For inotersen (Tegsedi®): 4 syringes per 28 days
For patisiran (Onpattro®): See Appendix B

TYMLOS

MEDICATION(S)
TYMLOS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
BMD T-score, FRAX.

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an endocrinologist or rheumatologist

COVERAGE DURATION
May be approved for up to 2 years, ensuring the cumulative duration of osteoanabolic therapy does not exceed 2 years in a lifetime . Duration of osteoanabolic therapy is defined as cumulative duration spent on any of the three therapies: abaloparatide. teriparatide, or romosozumab.

OTHER CRITERIA
For the treatment or prevention of osteoporosis, must meet ONE of the following criteria:
1. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures
2. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 and high risk for fracture, defined as one of the following:
a. Age more than 80 years
b. Chronic glucocorticoid use
c. Documented increased fall risk
3. Patient has a spine or hip BMD T-score less than or equal to -2.5 and one of the following:
a. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy

b. Documented contraindication or intolerance to therapy with all of the following: 1. denosumab, 2. oral bisphosphonate (e.g., alendronate), and 3. IV bisphosphonate therapy (i.e., zoledronic acid)
4. Patient has a spine or hip BMD T-score between -1.0 and -2.5 and BOTH of the following:
a. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%:
b. One of the following:
i. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
ii. Documented contraindication or intolerance to therapy with all of the following:
1. Denosumab
2. Oral bisphosphonate (e.g., alendronate)
3. IV bisphosphonate therapy (i.e., zoledronic acid)

UCERIS

MEDICATION(S)
BUDESONIDE ER, UCERIS 9 MG ER TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for patients 18 years and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 8 weeks.

OTHER CRITERIA
For budesonide extended release tablets (Uceris®)
1. Documented trial, failure, intolerance or contraindication to treatment with an aminosalicylate (e.g., sulfasalazine, mesalamine) AND
2. Documented trial, failure, intolerance or contraindication to one of the following oral corticosteroids: dexamethasone, hydrocortisone, methylprednisolone, prednisone or budesonide extended release capsule
For budesonide foam (Uceris®):
1. Documented trial, failure, intolerance or contraindication to a rectal mesalamine product AND
2. Documented trial, failure, intolerance or contraindication to a rectal steroid product (i.e hydrocortisone rectal enema)
The initial approval of Uceris® tablets and foam will allow for an 8-week treatment course. Further approval for Uceris® requires medical rationale why additional treatment is warranted and if patient is not on maintenance therapy for ulcerative colitis why it is not appropriate.

VASCEPA

MEDICATION(S)
VASCEPA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Triglyceride level, low-density lipoprotein cholesterol (LDL-C) levels.

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
For Hypertriglyceridemia all of the following must be met:
1. Trial (defined as 2 months of therapy), failure, or contraindication to a formulary agent to treat very high triglycerides such as fenofibrate.
2. A triglyceride level within the past 6 months that is greater than 500 mg/dL.

For ASCVD Risk Prevention all of the following must be met:
1. One of the following:
a. Established atherosclerotic heart disease as defined as one or more of the following:
i. Documented multivessel coronary artery disease (equal or greater than 50% stenosis in at least two major epicardial coronary arteries), prior myodardial infarction (MI), or hospitalization for non-ST elevation acute coronary syndrome.

ii. Documented cerebrovascular or carotid artery disease
iii. Documented peripheral arterial disease OR
b. Diabetes mellitus and two or more of the following additional risk factors for cardiovascular disease:
i. Men equal to or greater than 55 years of age or women equal to or greater than 65 years of age
ii. Hypertension
iii. High-density lipoprotein cholesterol (HDL-C) equal to or less than 40 mg/dL for men or equal to or less than 50 mg/dL for women
iv. High-sensitivity C-reactive protein (hs-CRP) greater than 3.0 mg/dL
v. Reduced kidney function (eGFR less than 60 mL/min per 1.73m2)
vi. Current cigarette smoker or recently quit smoking cigarettes within the past 3 months
vii. Retinopathy
viii. Micro- or macro-albuminuria
ix. Ankle-brachial index less than 0.9 without symptoms of intermittent claudication
2. Current use of a high-intensity statin therapy for at least 4 weeks or documented statin intolerance at any dose. Statin intolerance is defined as intolerable muscle side effects or biomarker changes (such as elevations of creatinine kinase) that decrease or resolve after discontinuation of therapy with statin.
3. A triglyceride level within the past 6 months that is equal to or greater than 150 mg/dL.
4. A low-density lipoprotein cholesterol (LDL-C) level within the past 6 months that is less than or equal to 100 mg/dL.

VEREGEN

MEDICATION(S)
VEREGEN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for 4 months. Reauthorization will not be approved, since safety and effectiveness beyond 16-weeks, or for multiple treatment courses has not been established.

OTHER CRITERIA
Documented trial, failure, intolerance, or contraindication to imiquimod 5% cream packets (Aldara®).

VIBERZI

MEDICATION(S)
VIBERZI

COVERED USES
N/A

EXCLUSION CRITERIA
Patients without a gallbladder

REQUIRED MEDICAL INFORMATION
1. Diagnosis of Irritable Bowel Syndrome with Diarrhea (IBS-D)
AND
2. Documentation of trial and failure, contraindication, or intolerance to loperamide
AND
3. Documentation of trial and failure, contraindication, or intolerance to one of the following drug classes:
a. Anti-spasmodic agent [e.g. dicyclomine (Bentyl®)]
b. Tricyclic antidepressants [e.g. amitriptyline (Elavil®)]

Reauthorization: Requires documentation of response to treatment, defined as improvement in stool consistency and abdominal pain

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gastroenterologist

COVERAGE DURATION
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A

VISTOGARD

MEDICATION(S)
VISTOGARD

COVERED USES
N/A

EXCLUSION CRITERIA
Non-emergent treatment of adverse reactions associated with fluorouracil or capecitabine

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 1 month.

OTHER CRITERIA
N/A

VMAT2 INHIBITORS

MEDICATION(S)
AUSTEDO, TETRABENAZINE, XENAZINE

COVERED USES
N/A

EXCLUSION CRITERIA
• Active suicidality
• Untreated or inadequately treated depression
• Hepatic Impairment
• Use in combination with monoamine oxidase inhibitors, other VMAT2 inhibitors or reserpine

REQUIRED MEDICAL INFORMATION
For chorea associated with Huntington disease, all of the following must be met:

1. Diagnosis of Huntington Disease as defined by all of the following:
a. DNA testing showing CAG expansion of more than 37
AND
b. Family history (if known)
AND
c. Classic presentation (choreiform movements, psychiatric problems, and dementia).
AND
2. Documentation that chorea is causing functional impairment.
AND
3. For Austedo®: Documented trial (of at least 8 weeks) and failure or intolerance of tetrabenazine.

Reauthorization:

Documented benefit of therapy, as evidence by improved function through reduction in choreiform movements.

For Tardive Dyskinesia, all of the following criteria must be met:
1. Diagnosis of tardive dyskinesia secondary to therapy with a dopamine receptor blocking agent
2. Documentation of the member's baseline Abnormal Involuntary Movement Scale (AIMS) score
3. Documentation of moderate to severe tardive dyskinesia, as defined by a total score on items 1-7 of at least 8 or a score of 3 or 4 on item 8 (severity of abnormal movement overall) on the AIMS
4. Documentation of an adequate trial and failure (at least two months), contraindication, or intolerance to

one of the following medications:
a. Clonazepam
b. Amantadine
c. Gingko biloba

Reauthorization:

Documentation of positive clinical response to therapy, as demonstrated by improvement in AIMS

QUANTITY LIMITS:

Deutetrabenazine (Austedo®) 6 mg and 12 mg tablet: 4 per day
Deutetrabenazine (Austedo®) 9 mg tablet: 5 per day
Valbenazine (Ingrezza®) 40 mg and 80 mg capsule: 1 per day
Tetrabenazine (Xenazine®) 12.5 mg and 25 mg tablet: 4 per day

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist or psychiatrist

COVERAGE DURATION
Initial prior authorization will be approved for 3 months. Reauthorization may be approved for one year.

OTHER CRITERIA
N/A

XIFAXAN

MEDICATION(S)
XIFAXAN

COVERED USES
N/A

EXCLUSION CRITERIA
More than three (3) treatment courses for IBS-D.

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For irritable bowel syndrome with diarrhea (IBS-D): Must be prescribed by, or in consultation with, a gastroenterologist

COVERAGE DURATION
IBS-D (550 mg tablets):
Initial authorization: One-time 14-day treatment course per 3 months
Reauthorization: Will be approved for up to two additional 14 day treatment courses (total of three treatment courses per lifetime)
Traveler’s diarrhea (200-mg tablets): One-time 3-day treatment course (Quantity of 9 tablets)

Hepatic Encephalopathy (550 mg tablets): Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
Traveler’s diarrhea (200 mg tablets):
Diagnosis of traveler’s diarrhea caused by noninvasive strains of Escherichia coli. Xifaxan® is not covered if documentation shows diarrhea that is complicated by fever or blood in stool.

Hepatic Encephalopathy (550 mg tablets): Documentation of trial and failure, contraindication or intolerance to lactulose

Irritable Bowel Syndrome with Diarrhea (IBS-D) with or without small intestinal bacterial growth (SIBO) for 550-mg tablets): Commercial and HIM only:
1. Inadequate treatment response to dietary modification (such as low carbohydrates, low intake of gas producing foods, etc.)
2. Documentation of trial and failure, contraindication, or intolerance to an opioid mu receptor agonist [e.g. loperamide (Imodium®)]
3. Documentation of trial and failure, contraindication, or intolerance to ONE of the following medications:
a. Anti-spasmodic agent [e.g. dicyclomine (Bentyl®)]
b. Tricyclic antidepressants (TCAs) or Selective Serotonin Reuptake (SSRIs) [e.g. amitriptyline (Elavil®), fluoxetine (Prozac®), or sertraline (Zoloft®)]

Reauthorization in IBS-D requires documentation of initial response to treatment with rifaximin and recurrence of IBS-D symptoms. Limited to three total14-day course treatments (initial treatment and two reauthorizations).

QUANTITY LIMIT:

200-mg and 550-mg tablets: 3 tablets per day

XURIDEN

MEDICATION(S)
XURIDEN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Written by or in consultation with an endocrinologist, hematologist, medical geneticist, or metabolic specialist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA
1. Confirmed diagnosis of hereditary orotic aciduria by an appropriate specialist
2. Documented therapeutic failure of uridine dietary supplements

XYREM

MEDICATION(S)
XYREM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For treatment of narcolepsy with cataplexy the following criteria must be met:
a. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay)
b. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months
c. Documentation of presence of cataplexy
2. For treatment of excessive daytime sleepiness in narcolepsy without cataplexy the following criteria must be met:
a. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay)
b. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months
c. Other causes of sleepiness have been ruled out or treated (i.e. obstructive sleep apnea, shift work, effects of substances or medications or their withdrawal, other sleep disorders)
d. Documentation of a three (3)-month trial and failure, incomplete response, intolerance, or contraindication to both of the following:
i. Stimulant (e.g., amphetamine, methylphenidate)
ii. Modafinil or armodafinil

Reauthorization:

Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks.

QUANTITY LIMIT:

Xyrem® is limited to 9 grams per day, which is 540 mL/30 days.
There is no evidence of additional benefit achieved with Xyrem® doses over 9 grams per day.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by a sleep specialist or neurologist

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA
N/A

ZYFLO CR

MEDICATION(S)
ZILEUTON ER, ZYFLO CR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Documentation that the patient has been taking an inhaled corticosteroid controller medication (e.g., Flovent HFA®) continuously for at least one month and continues to have persistent asthma symptoms (e.g., coughing, wheezing, shortness of breath)
AND
2. Documentation of an adequate trial and failure, contraindication or intolerance to both montelukast and zafirlukast. An adequate trial and failure is defined as at least one month of continuous use

AGE RESTRICTION
Use may be approved for individuals 12 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
N/A