HEALTH SHARE/PROVIDENCE (OHP)

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. Prior Authorization for individual drugs and categories of drugs may be required to ensure that the drugs prescribed are indicated for conditions funded by OHP and consistent with the drug formulary. 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 503-574-8200 or 1-800-898-8174 (TTY: 711). Service is available five days a week, Monday through Friday, between 8 a.m. and 6 p.m.

ACNE MEDICATIONS

MEDICATION(S)

ACNE CONTROL CLEANSER, ACNE FOAMING WASH, ACNE MEDICATION 10% GEL, ACNE MEDICATION 5% GEL, ACNE TREATMENT, ACNECLEAR, ADAPALENE 0.1% GEL, ADAPALENE 0.3% GEL, ADVANCED EXFOLIATING CLEANSER, AMNESTEEM, ATRALIN, AVITA 0.025% CREAM, BENZACLIN, BENZAMYCIN, BENZOYL PEROXIDE 10% GEL, BENZOYL PEROXIDE 10% WASH, BENZOYL PEROXIDE 5% GEL, BENZOYL PEROXIDE 5% WASH, BENZOYL PEROXIDE 6% CLEANSER, PR BENZOYL PEROXIDE 7% WASH, BP, BP WASH 10% LIQUID, BP WASH 5% LIQUID, BP WASH 7% LIQUID, BPO-10, BPO-5, CLARAVIS, CLEAN-CLEAR CONTINUOUS CONTROL, CLEOCIN T, CLINDACIN ETZ 1% PLEDGET, CLINDACIN P, CLIND PH-BENZOYL PEROX 1.2-5%, CLINDAMYCIN PH 1% GEL, CLINDAMYCIN PH 1% SOLUTION, CLINDAMYCIN PHOS 1% PLEDGET, CLINDAMYCIN PHOSP 1% LOTION, CLINDAMYCIN-BENZOYL PEROXIDE, DAYLOGIC ACNE FOAMING WASH, DAYLOGIC ACNE TREATMENT, DIFFERIN 0.1% GEL, DIFFERIN 0.3% GEL, DUAC, EFFACLAR ADAPALENE, ERY, ERYGEL, ERYTHROMYCIN 2% GEL, ERYTHROMYCIN 2% PLEDGETS, ERYTHROMYCIN 2% SOLUTION, ERYTHROMYCIN-BENZOYL PEROXIDE, FOAMING ACNE FACE WASH, ISOTRETINOIN 10 MG CAPSULE, ISOTRETINOIN 20 MG CAPSULE, ISOTRETINOIN 30 MG CAPSULE, ISOTRETINOIN 40 MG CAPSULE, KLARON, MYORISAN, NEUAC GEL, PACNEX, PANOXYL 10% ACNE FOAMING WASH, PERSA-GEL, PR BENZOYL PEROXIDE, RETIN-A 0.01% GEL, RETIN-A 0.025% CREAM, RETIN-A 0.05% CREAM, RETIN-A 0.1% CREAM, SODIUM SULFACETAMIDE 10% LOTN, SULFACETAMIDE SOD 10% TOP SUSP, TRETINOIN 0.01% GEL, TRETINOIN 0.025% CREAM, TRETINOIN 0.05% CREAM, TRETINOIN 0.05% GEL, TRETINOIN 0.1% CREAM, ZENATANE

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For acne: Documentation that patient has one (1) of the following conditions (must be supported by chart notes):

a. Acne Fulminans

b. Acne Conglobata with recurrent abscesses or communicating sinuses

c. Severe Cystic Acne with persistent or recurrent inflammatory nodules and cysts AND ongoing scarring

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

ACUTE HEREDITARY ANGIOEDEMA THERAPY

MEDICATION(S)

BERINERT, FIRAZYR, ICATIBANT, KALBITOR, RUCONEST

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial authorization: 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 (6) 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 (1) 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:

1. C1-Inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or

2. 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),ANGPT1, PLG, KNG1 gene mutation

OR

ii. Positive family history for HAE AND attacks lack response with high dose antihistamines or corticosteroids.

AND

3. For coverage of Berinert®, Kalbitor®, Firazyr®, or Ruconest®: For patients not established on therapy only: Documentation of trial and failure or contraindication to generic icatibant

For reauthorization:

Documentation must be provided showing benefit of therapy with reduction of length and severity of HAE

attack episodes.

For quantities exceeding the formulary quantity limit:
1. Documentation of frequent HAE attacks defined as greater than or equal to two (2) attacks per month on average.

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

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 one (1) year.

OTHER CRITERIA
N/A

ADAKVEO

MEDICATION(S)
ADAKVEO

COVERED USES
N/A

EXCLUSION CRITERIA
Used in combination with voxelotor (Oxbryta®)

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Confirmed medical history or diagnosis of sickle cell disease
2. Patient has experienced at least two (2) sickle cell-related pain crises in the prior year
3. Documentation that patient meets one of the following:
a. Patient will continue taking hydroxyurea with the requested therapy and patient has been on a maximally tolerated dose of hydroxyurea for at least six (6) months
b. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least six (6) months
c. Patient has had an intolerance or contraindication to hydroxyurea (For many patients myelosuppression is dose-dependent and reversible, intolerance due to myelosuppression will only be considered if patient continues to experience myelosuppression despite dose adjustments)

Reauthorization: Documentation that the number or severity of sickle cell-related pain crises has decreased from baseline

AGE RESTRICTION
May be approved for patients 16 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a hematologist or a provider experienced with the treatment of sickle cell disease.

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

OTHER CRITERIA
N/A

ADDYI

MEDICATION(S)
ADDYI

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

Coverage for Oregon Medicaid is limited to conditions that have been designated as a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

EXCLUSION CRITERIA
Sexual dysfunction without a diagnosis listed above.

REQUIRED MEDICAL INFORMATION
For initial authorization, all of the following must be met:
1. Patient is female and pre-menopausal
2. Patient must have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) that is causing marked distress or interpersonal difficulty
3. Documentation that the patient's condition is NOT due to any of the following:
a. A co-existing medical or psychiatric condition,
b. Problems within the relationship, or
c. The effects of a medication or other drug substance

Reauthorization requires documentation of all of the following:
1. Patient continues to be pre-menopausal
2. Documentation of positive response to the medication

AGE RESTRICTION
Approved for ages 18 years and older.

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

ADULT LONG ACTING STIMULANT MEDICATIONS

MEDICATION(S)

ADDERALL XR, APTENSIO XR, CONCERTA, COTEMPLA XR-ODT, DAYTRANA, DEXEDRINE, DEXMETHYLPHENIDATE HCL ER, DEXTROAMPHETAMINE SULFATE ER, DEXTROAMPHETAMINE-AMPHET ER, DYANAVEL XR, FOCALIN XR, METADATE ER, METHYLPHENIDATE ER, METHYLPHENIDATE ER (LA), METHYLPHENIDATE HCL CD, METHYLPHENIDATE HCL ER (CD), METHYLPHENIDATE LA, MYDAYIS, QUILLICHEW ER, RELEXXII, RITALIN LA, VYVANSE, ZENZEDI 15 MG TABLET, ZENZEDI 2.5 MG TABLET, ZENZEDI 20 MG TABLET, ZENZEDI 30 MG TABLET, ZENZEDI 7.5 MG TABLET

COVERED USES

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. Stimulants may be covered for Attention Deficit Hyperactivity Disorder (diagnosis code F90.x) or narcolepsy (diagnosis codes G47.41, G47.411, G47.419, G47.42, G47.421, or G47.429) subject to criteria below. Vyvanse® may be covered for binge eating disorder subject to criteria below.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial authorization, all of the following criteria

1. Requests for preferred agents (see Table 1 below) may be covered with one of the following diagnoses, confirmed while an adult, as follows:

a. Attention Deficit Hyperactivity Disorder (ADHD) – diagnosis code F90.x

b. Narcolepsy

2. Requested regimen is within FDA approved age range and maximum daily dose outlined in Table 2 and Table 3 below

a. Requests outside of these limits will require documentation that the drug regimen was developed by, or in consultation with, a psychiatrist, developmental pediatrician, psychiatric nurse practitioner, sleep specialist or neurologist. Continuation of existing therapy once up to 90 days may be covered to allow time to consult with a mental health specialist.

3. Requested regimen is for once daily dosing. Requests for more than once daily dosing must meet one (1) of the following:

a. The prescribed dose cannot be achieved using a lesser quantity of a higher strength (i.e. utilize one 20 mg capsule instead of two 10 mg capsules),

b. Documentation that the drug regimen was developed by, or in consultation with, a psychiatrist, developmental pediatrician, psychiatric nurse practitioner, sleep specialist or neurologist. Continuation of

existing therapy once up to 90 days may be covered to allow time to consult with a mental health specialist.
c. Dosing regimens of long-acting stimulants that exceed two times daily are not considered medically necessary and are not covered.
4. Requests for non-preferred agents may be covered if all of the following criteria are met:
a. Confirmed diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) or narcolepsy
i. Binge eating disorder (Vyvanse® only) will be approved with a confirmed diagnosis supported by clinical documentation
b. Documented trial, of at least 4 weeks, of at least two different preferred agents (see Table 1) with inadequate response (e.g., minimal to no improvement in symptoms)

For patients established on therapy, all of the following criteria must be met:
1. Patient has a confirmed current diagnosis of one of the following funded conditions:
a. Attention Deficit Hyperactivity Disorder (ADHD)
b. Narcolepsy
c. Binge eating disorder
2. Documentation of positive response to therapy
3. Requested regimen is within FDA approved age range and maximum daily dose outlined in Table 2 and Table 3 below
a. Requests outside of these limits will require documentation that the drug regimen was developed by, or in consultation with, a psychiatrist, developmental pediatrician, psychiatric nurse practitioner, sleep specialist or neurologist. Continuation of existing therapy once up to 90 days may be covered to allow time to consult with a mental health specialist.
4. Requested regimen is for once daily dosing. Requests for more than once daily dosing must meet one (1) of the following:
a. The prescribed dose cannot be achieved using a lesser quantity of a higher strength (i.e. utilize one 20 mg capsule instead of two 10 mg capsules),
b. Documentation that the drug regimen was developed by, or in consultation with, a psychiatrist, developmental pediatrician, psychiatric nurse practitioner, sleep specialist or neurologist. Continuation of existing therapy once up to 90 days may be covered to allow time to consult with a mental health specialist.
c. Dosing regimens of long-acting stimulants that exceed two times daily are not considered medically necessary and are not covered

QUANTITY LIMIT:
All long-acting formulation of stimulant medications are covered at one tablet/capsule per day (if prior authorization is approved), with the following exceptions:
• Adderall XR® (dextroamphetamine-amphetamine ER) 20mg capsules (2 capsules per day)
• Concerta® (methylphenidate ER) 36mg (2 tablets per day)

If requested quantities exceed formulary quantity limit, additional criteria will apply. Please refer to Medical

Policy #ORPTCCNS029 - Long-Acting Stimulant Medications Quantity Limit.

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

AEMCOLO

MEDICATION(S)
AEMCOLO

COVERED USES
N/A

EXCLUSION CRITERIA
Use for travel (when a member has not already acquired travelers' diarrhea) is a benefit exclusion for the Oregon Health Plan and is excluded from coverage.

REQUIRED MEDICAL INFORMATION
Diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli. Rifamycin is not covered if documentation shows diarrhea that is complicated by fever or blood in stool.

QUANTITY LIMIT:
12 tablets per 28 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for a 3-day treatment course

OTHER CRITERIA
N/A

ALBENZA, EMVERM

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

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For the treatment of pinworms (Enterobius vermicularis):
i. Documented trial, failure, intolerance, or contraindication to pyrantel pamoate (available over the counter)
OR
2. For diagnoses other than pinworm (Enterobius vermicularis):
i. Must be FDA approved or be a medically accepted indication (i.e., guideline directed therapy or compendia supported as listed in either the American Hospital Formulary System or Drugdex).
ii. 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 may be waived if diagnosis has been confirmed through validated laboratory testing/identification.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
See “Required Medical Information”

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

OTHER CRITERIA
N/A

ALINIA

MEDICATION(S)
ALINIA, NITAZOXANIDE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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

For diagnoses other than listed above:
1. Must be FDA approved or be a medically accepted indication (i.e., guideline directed therapy or compendia supported as listed in either the American Hospital Formulary System or Drugdex).
2. Must be prescribed by or in consultation with an infectious disease specialist or gastroenterologist.
3. Length of coverage will be 3 to 10 days depending on appropriate treatment duration for the diagnosis.

QUANTITY LIMIT:
Nitazoxanide (Alinia®) 500 mg tablets: 2 tablets per day
Nitazoxanide (Alinia®) 100 mg/ 5 ml suspension: 50 mL per day

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For diarrhea caused by Cryptosporidium parvum in patients without HIV and diarrhea caused by Giardia

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.

For all other indications: authorization will be approved for 3 to 10 days depending on diagnosis.

OTHER CRITERIA
N/A

ALPHA-1 PROTEINASE INHIBITORS

MEDICATION(S)
ARALAST NP, GLASSIA, PROLASTIN C, ZEMAIRA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of:
1. One (1) of the following:
a. Serum alpha-1 antitrypsin (AAT) concentrations less than 11 uM/L (approximately 57 mg/dL by nephelometry or 80mg/dL by immunodiffusion)
b. Patient has one of the high-risk phenotypes by protease inhibitor (PI) typing: PI*ZZ, PI*Z(null), PI*(null,null), or PI*SZ homozygotes
AND
2. Diagnosis of emphysema confirmed by one (1) of the following:
a. Forced expiratory volume per one second (FEV1) of 35 to 65% of predicted volume
b. Rapid lung function decline as evidence by reduction of FEV1 of 100 mL/year or greater
AND
3. Documentation that the patient has never smoked or has abstained from smoking for at least the previous 6 months

QUANTITY LIMIT:
60 mg/kg infused every 7 days, subject to audit.
Note: Dose may be rounded down to the nearest gram (0.5 gm for Aralast®) within 10% of calculated dose.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization for 6 months. Reauthorization for one year.

OTHER CRITERIA

N/A

AMIFAMPRIDINE

MEDICATION(S)
FIRDAPSE, RUZURGI

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

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 or posaconazole: Documented failure, intolerance, or contraindication to itraconazole
4. For prophylaxis of invasive Aspergillus or Candida infections: posaconazole or voriconazole may be covered for severely immunocompromised patients. For example:
a. Hematopoietic stem cell transplant recipient with graft-versus-host disease
b. Current diagnosis of cancer currently undergoing chemotherapy or radiation
c. HIV/AIDS
d. Lung transplant or high risk non-lung solid organ transplant recipients
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
OR
b. Documentation of trial and failure, intolerance or contraindication to topical therapy to treat the condition
7. For treatment of mucormycosis: isavuconazonium or posaconazole 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)

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 three (3) months. Reauthorization will be approved for up to one (1) year.

OTHER CRITERIA
N/A

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 treatment of acute malaria (Coartem® only):
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 leucovorin and sulfadiazine, or clindamycin 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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA

N/A

APOMORPHINE

MEDICATION(S)
APOKYN, KYNMOBI

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

ARIKAYCE

MEDICATION(S)
ARIKAYCE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Documentation of a confirmed diagnosis of Mycobacterium avium complex (MAC) lung infection by MAC-positive sputum or bronchoscopy cultures
AND
2. Documentation that the patient is unable to achieve negative sputum cultures after a minimum of 6 consecutive months of a standard guideline-based therapy (GBT). Guideline-based therapy is a three-drug oral antibiotic regimen composed of a macrolide (clarithromycin or azithromycin), ethambutol and rifamycin (rifabutin).
AND
3. Documentation that organism is susceptible to amikacin

Reauthorization requires documentation of negative sputum cultures.

QUANTITY LIMIT:
28 vials per month (8.4 ml/day)

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an infectious disease specialist, or pulmonologist

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

OTHER CRITERIA
N/A

BENLYSTA

MEDICATION(S)
BENLYSTA

COVERED USES
N/A

EXCLUSION CRITERIA
Belimumab will not be approved if any of the following are present:
1. Severe active central nervous system lupus
2. Current use of other biologic immunomodulator
3. Documentation of no previous use of dialysis in the past 12 months or currently using dialysis

REQUIRED MEDICAL INFORMATION
For Systemic Lupus Erythematous (SLE) and active lupus nephritis:
All of the following must be met:
1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) or active lupus nephritis by a rheumatologist or nephrologist
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. For SLE without Active Lupus Nephritis:
i. Oral corticosteroid(s)
ii. Azathioprine
iii. Methotrexate
iv. Mycophenolate mofetil
v. Hydroxychloroquine
vi. Chloroquine
vii. Cyclophosphamide
b. For SLE with Active Lupus Nephritis:

i. mycophenolate for induction followed by mycophenolate for maintenance, OR
ii. cyclophosphamide for induction followed by azathioprine for maintenance.
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, reduction of renal related events)
Patient currently receiving standard therapy for SLE and active lupus nephritis

QUANTITY LIMIT:
• Belimumab 200 mg/mL single-dose prefilled auto injector and glass syringe for subcutaneous injection: 4 mL per 28 days
o Adults with SLE without active lupus nephritis allowed loading dose: none
o Adults with SLE with active lupus nephritis allowed loading dose: 400-mg dose (two 200-mg injections) once weekly for 4 doses, then 200 mg once weekly thereafter
• 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
o Applicable to adults with SLE or active lupus nephritis and pediatric patients with SLE
• 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

AGE RESTRICTION
For SLE without active lupus nephritis:
Age 5 years and older for IV infusion
Age 18 years and older for subcutaneous injection

For SLE with Active Lupus Nephritis:
Age 18 years and older for IV infusion or subcutaneous injection

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

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

OTHER CRITERIA

N/A

BOTULINUM TOXIN

MEDICATION(S)

JEUVEAU

COVERED USES

N/A

EXCLUSION CRITERIA

• When the above criteria are not met, botulinum toxin is considered investigational and not covered.
• Botulinum toxin is considered cosmetic and is not covered for the treatment of glabellar lines and/or fine wrinkles on the face.
o PrabotulinumtoxinA (Jeuveau®) will not be covered as it is only FDA approved for the treatment of glabellar lines and/or fine wrinkles on the face.

REQUIRED MEDICAL INFORMATION

OnabotulinumtoxinA (Botox®) may be covered for the following indications when criteria are met:
1. Chronic migraine headaches in adults when all of the following is met:
a. Documentation of at least 15 headache days per month with headaches lasting 4 hours or longer
b. Documentation of trial and failure, intolerance, or contraindication to at least TWO of the following classes used for migraine prevention. Trial and failure is defined as inadequate response following a minimum three (3) months of consistent use.
i. Antidepressants (e.g., amitriptyline, venlafaxine)
ii. Beta-blockers (e.g., metoprolol, propranolol, timolol)
iii. Antiepileptic's (e.g., divalproex, valproate, topiramate)
c. Combination therapy with Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists (e.g., Aimovig®, Emgality®, Ajovy®) is considered investigational and is not covered
2. Upper and lower limb spasticity in patients at least 2 years of age
3. Cervical dystonia in adults
4. Strabismus and blepharospasm associated with dystonia in patients at least 12 years of age
5. Severe axillary hyperhidrosis in adults after documented trial and failure, intolerance or contraindication to topical agents
a. Note: The safety and effectiveness of onabotulinumtoxinA for hyperhidrosis in other body areas have not been established.
6. Overactive bladder in adults with:
a. Symptoms of urge urinary incontinence, urgency, and frequency
b. Documented trial and failure, intolerance, or contraindication to at least one month of anticholinergic medication (e.g., oxybutynin, tolterodine)
7. Urinary incontinence in adults:

a. Due to detrusor over activity related to a neurologic condition (e.g., spinal cord injury, multiple sclerosis)
b. Documented trial and failure, intolerance, or contraindication at least one month of anticholinergic medication (e.g., oxybutynin, tolterodine)
8. Excessive salivation due to advanced Parkinson's disease
9. Hemifacial spasm
10. Chronic anal fissure when all of the following is met:
a. Prescribed by, or in consultation with, a gastroenterologist or colorectal surgeon
b. Documentation of trial and failure, intolerance, or contraindication to at least 6 weeks of therapy with either topical nitrates or topical calcium channel blockers
c. One of the following:
i. Documentation that the patient is not a good candidate for surgery or appropriate medical rationale is provided for avoiding surgery
ii. Botox® is to be used in conjunction with fissurotomy
d. The use of Botox® in combination with sphincterotomy or anal advancement flap is considered experimental and investigational and will not be covered

1. AbobotulinumtoxinA (Dysport®) may covered for the following indications:
a. Spasticity in adults
b. Cervical dystonia in adults
c. Upper and lower limb spasticity in patients at least 2 years of age
d. Blepharospasm in adults

2. IncobotulinumtoxinA (Xeomin®) may covered for the following indications:
a. Chronic sialorrhea in patients 2 years and older
b. Upper limb spasticity in patients at least 2 years of age
c. Cervical dystonia in adults
d. Blepharospasm in adults

3. RimabotulinumtoxinB (Myobloc®) may covered for the following indications:
a. Cervical dystonia in adults
b. Chronic sialorrhea in adult patients

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA

N/A

BPH TREATMENT- CIALIS, RAPAFLO

MEDICATION(S)
CIALIS 5 MG TABLET, RAPAFLO, SILODOSIN, TADALAFIL 5 MG TABLET

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 Rapaflo®: Documentation of an adequate trial and failure (defined as daily use for at least 4 weeks of therapy without improvement in signs and symptoms of BPH), or intolerance, to two formulary alpha-adrenergic blockers (e.g., tamsulosin, doxazosin, terazosin, alfuzosin).

For tadalafil (Cialis®) 5 mg daily for signs and symptoms of benign prostatic hyperplasia (BPH): Documentation of an adequate trial and failure (defined as daily use for at least 4 weeks of therapy without improvement in signs and symptoms of BPH), 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)

QUANTITY LIMIT:
Tadalafil (Cialis®) 5 mg: 30 tablets 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

BRAND OVER GENERIC

MEDICATION(S)
GLEEVEC, TECFIDERA

COVERED USES
N/A

EXCLUSION CRITERIA
Brand formulations will not be approved solely due to financial reasons (e.g., patient has coupon card for brand formulation).

REQUIRED MEDICAL INFORMATION
One of the following criteria must be met:
1. Patient has a documented allergy to an excipient found in all generic manufacturers' products
2. Patient has had a therapeutic failure to the generic formulation. This is defined as the patient taking the medication as prescribed for an adequate duration, a trial on multiple generic manufacturers' products, and the therapeutic failure cannot be attributed to inadequate dosing
3. Documented medical rationale for requiring use of brand name formulation over therapeutically equivalent generic formulation. If the rationale provided is related to the Food & Drug Administration's definition of generic bioequivalence, high-quality medical literature must be provided showing there are clinically meaningful differences between the specific formulations in terms of efficacy and/or safety.

QUANTITY LIMIT:
Quantity limits, that apply to a generic formulation, will also apply to brand name formulation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

BRINEURA - MEDICAL BENEFIT

MEDICATION(S)
BRINEURA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Tests to confirm a diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) as required for “other criteria”, baseline CLN2 disease clinical rating scale 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
May be covered for ages 3-17 years

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

COVERAGE DURATION
Initial approval and reauthorization will be for 1 year

OTHER CRITERIA
Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) with all of the following:
1. Deficiency of tripeptidyl peptidase 1 (TPP1) enzyme activity, in the setting of normal activity of a control enzyme such as palmitoyl-protein thioesterase 1 (PPT1) and/or ?-galactosidase (a sample of leukocytes, dried blood spot, fibroblasts, or saliva may be used) AND
2. Genetic testing revealing one pathogenic mutation on each parental allele of TPP1/CLN2 AND
3. Documentation of symptomatic disease (seizures, changes in gait, falls, difficulty in ambulating, loss of language/delay in language development, visual failures) AND
4. Baseline Motor Domain of the CLN2 Clinical Rating Scale score of at least 1 (Appendix 1)

Reauthorization requires documentation of response to therapy, as defined as:
1) No more than a 1-point decline in the Motor Domain of the CLN2 Clinical Rating Scale AND

2) Motor Domain of the CLN2 Clinical Rating Scale score remains above 0.

BRISDELLE

MEDICATION(S)
BRISDELLE, PAROXETINE MESYLATE

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented trial, failure, intolerance, or contraindication to one of the following agents: paroxetine, escitalopram, venlafaxine, citalopram, gabapentin, or clonidine.

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

BUPRENORPHINE - PROBUPHINE/SUBLOCADE - MEDICAL BENEFIT

MEDICATION(S)
PROBUPHINE, SUBLOCADE

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
Treatment of chronic pain

REQUIRED MEDICAL INFORMATION
For Probuphine®:
Initial Authorization:
1. Documentation of opioid use disorder
2. Patient has been clinically stable for at least 3 months on 8 mg per day or less of a transmucosal buprenorphine product (i.e. Subutex® or Suboxone® sublingual tablet or generic equivalent). (The FDA indications specify that maintenance dose should not be tapered to a lower dose for the sole purpose of transitioning to Probuphine®)
3. Medical rational of why patient cannot be continued on maintenance therapy with a transmucosal buprenorphine product.
4. Documentation that Probuphine® will be used along with counseling and/or psychosocial support
Reauthorization:
1. Documentation that patient has experienced treatment success (i.e. abstinence from other opioids)
2. Documentation that Probuphine® will be continue to be used along with counseling and/or psychosocial support
3. Documentation that this is the second course of therapy to be inserted into the contralateral arm. (Treatment beyond 2 courses has not been studied in clinical trials and is not considered medically necessary).

For Sublocade®:
Initial authorization:
1. Documentation of opioid use disorder
2. Patient is currently maintained or will be maintained on an 8mg to 24mg per day dose of oral, sublingual, or transmucosal buprenorphine product equivalent for at least 7 days prior to initiation of extended-release buprenorphine injection
3. Medical rationale of why therapy with a transmucosal buprenorphine product is not appropriate for this patient
4. Documentation that Sublocade® will be used along with counseling and/or psychosocial support

Reauthorization:
1. Documentation that patient has experienced treatment success (i.e. abstinence from other opioids)
2. Documentation that patient continues to receive Sublocade® along with counseling and/or psychosocial support

QUANTITY LIMIT:
For Probuphine®: 1 kit (4 implants) per 6 months, lifetime limit of 1 insertion in each arm (2 kits)
For Sublocade®: 1 injection per 28 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For Probuphine®: Initial authorization and reauthorization will be approved for 6 months. Coverage will be limited to two courses of treatment (one insertion into each arm). Treatment for longer than 12-months (2 treatment courses) has not been studied in clinical trials and is not considered medically necessary.

OTHER CRITERIA
N/A

CABLIVI

MEDICATION(S)
CABLIVI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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 (2) 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:
One (1) vial per day

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

N/A

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

MEDICATION(S)
NURTEC ODT, UBRELVY

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
Concurrent use of a strong CYP3A4 inhibitor (e.g. ketoconazole, itraconazole, clarithromycin).
Concurrent use with a CGRP used for migraine prophylaxis

REQUIRED MEDICAL INFORMATION
Diagnosis of migraine headaches AND one of the following:
• Trial of and inadequate response or intolerance to two (2) oral triptans (e.g., sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan) and one (1) additional triptan formulation (e.g. oral disintegrating tablet, nasal spray, injection) OR
• One of the following cardiovascular or non-coronary vascular contraindications to use of triptans:
o Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina)
o History of stroke or transient ischemic attack (TIA)
o Peripheral vascular disease
o Ischemic bowel disease
o Uncontrolled hypertension

Reauthorization: Documentation of treatment success as demonstrated reduction of migraine pain or freedom from migraine symptoms and, if applicable, demonstration that additional quantities continue to be medically necessary

QUANTITY LIMIT:
Ubrogepant tablets: 10 tablets per 30 days
Rimegepant tablets: 8 tablets per 30 days

Quantities up to 16 tablets per 30 days will be approved if requested by a provider with supporting medical rationale that the patient is on prophylactic therapy (e.g. divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, or venlafaxine), the patient is still experiencing more than two (2) headache days per week regardless of prophylactic therapy, and policy criteria are met.

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

OTHER CRITERIA

N/A

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

MEDICATION(S)

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

COVERED USES

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization for migraine prophylaxis:

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

AND

2. Documentation of trial and failure (of at least six weeks) of at least one prophylactic medication from all of the following categories, or intolerance/contraindication to each of the following classes:

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

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

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

AND

3. Documentation that member has not received a botulinum toxin injection in the past two months

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. Documentation of trial and failure*, intolerance, or contraindication to all of the following prophylactic medications:

a. Verapamil

b. Melatonin

c. Lithium

AND

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

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

*An adequate trial and failure is defined as minimal to no improvement after at least six (6) weeks of therapy.

AGE RESTRICTION
Approved for 18 years of age and older

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

CAMBIA

MEDICATION(S)
CAMBIA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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.

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

CAR-T (KYMRIAH, YESCARTA) - MEDICAL BENEFIT

MEDICATION(S)
KYMRIAH, TECARTUS, YESCARTA

COVERED USES
N/A

EXCLUSION CRITERIA
1.Previous treatment with chimeric antigen receptor therapy or other genetically modified T-cell therapy
a. Repeat administration of CAR-T therapy is considered experimental and investigational because the effectiveness of this approach has not been established
2. History of allogenic stem cell transplantation and primary central nervous system (CNS) lymphoma
3. Presence of history of CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, brain metastases, or any autoimmune disease with CNS involvement
4. Active infection or inflammatory disorder (including hepatitis B or C, human immunodeficiency virus [HIV], active graft vs. host disease)

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes (e.g., original pathology report, treating oncologist chart notes) documenting medical rationale are required.

AGE RESTRICTION
KymriahTM:
1. Approved for 25 years of age or younger for acute lymphoblastic leukemia (ALL)
2. Approved for 18 years of age and older for relapsed or refractory large B-cell lymphoma
TecartusTM:
1. Approved for 18 years of age and older
YescartaTM:
1. Approved for 18 years of age and older

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

COVERAGE DURATION
2 months (limited to one treatment course per lifetime, with 4 doses of tocilizumab [Actemra®] at up to 800mg per dose).

OTHER CRITERIA
For all indications, the following criteria must be met:

1. Documentation of adequate bone marrow, cardiac, pulmonary and organ function (e.g., kidney) to minimize risks of serious adverse reactions (e.g., cytokine release syndrome)

For B-cell precursor acute lymphoblastic leukemia (ALL), KymriahTM may be approved when all of the following criteria are met:
1. Documentation of cluster of differentiation 19 (CD19) positive, B-cell precursor acute lymphoblastic leukemia (ALL), and
2. Disease is considered refractory, or in second or later relapse, as defined by any one of the following scenarios:
a. Second or later bone marrow relapse, or
b. Bone marrow relapse after allogenic stem cell transplant, or
c. Primary refractory (not achieving a complete response after 2 cycles of standard chemotherapy), or
d.Chemorefractory (not achieving a complete response after 1 cycle of standard chemotherapy for relapsed disease), and
3. Member is not eligible for allogenic stem cell transplant, and
4. For Philadelphia chromosome (Ph)-positive disease only: Have failed adequate trials of, contraindication, or intolerance to two (2) prior lines of tyrosine kinase inhibitor (TKI) therapy (e.g., imatinib, dasatinib, nilotinib, ponatinib)
5. Performance score on Karnofsky or Lansky Scale is greater than or equal to 50% or Eastern Cooperative Oncology Group (ECOG) performance score is 0-3
Note: For patients aged 18 years and younger with minimal residual disease (MRD) after consolidation therapy, NCCN guidelines have given category 2B recommendation for use as a single-agent therapy.

For relapsed or refractory large B-cell lymphoma, YescartaTM or KymriahTM may be approved when all of the following criteria are met:
1. Confirmed diagnosis of relapsed or refractory FDA approved large B-cell lymphomas (see FDA Approved Indications below/package insert)
2. Refractory or relapse to two (2) or more prior treatment regimens (e.g. TKI), and
a. For Follicular Lymphoma: Previous therapy must have included an anthracycline (e.g. doxorubicin) or anthracenedione-based regimen, unless contraindicated or if therapy was previously not tolerated
b. For CD20+ disease: Previous therapy must have included an anti-CD20 monoclonal antibody (e.g. rituximab), unless contraindicated or if therapy was previously not tolerated
3. Asymptomatic or minimally symptomatic with Eastern cooperative oncology group (ECOG) performance status 0-1
4. Member is not eligible for allogenic stem cell transplant

For relapsed or refractory mantle cell lymphoma (MCL), TecartusTM may be approved when all of the following criteria are met:
1. Histologically confirmed mantle-cell lymphoma [i.e. cyclin D1 overexpression or presence of the translocation t(11,14)]

2. Disease is considered relapsed or refractory
3. Previous use to the following therapy: anthracycline or bendamustine containing chemotherapy, an anti-CD20 monoclonal antibody, and BTK inhibitor therapy
4. Asymptomatic or minimally symptomatic with Eastern cooperative oncology group (ECOG) performance status 0-1

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 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 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 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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For use in gallstone dissolution, must be prescribed by, or in consultation with, 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
N/A

CHOLBAM

MEDICATION(S)
CHOLBAM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. Documentation of baseline liver function tests (LFTs)
AND
2. For bile acid synthesis disorder: documentation of a single enzyme defect
3. For peroxisomal disorder, including Zellweger spectrum disorders, both of the following criteria must be met:
a. Documentation of manifestations of at least one of the following:
i. Liver disease (e.g., jaundice, elevated serum transaminases)
ii. Steatorrhea
iii. Complications from decreased fat-soluble vitamin absorption (e.g., poor growth)
AND
b. The medication will be used as adjunctive therapy

For Reauthorization: Documentation of positive clinical response, as evidenced by an improvement in LFTs

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 for 6 months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
N/A

CONSTIPATION AGENTS

MEDICATION(S)
AMITIZA, LINZESS, LUBIPROSTONE, MOTEGRITY, MOVANTIK, RELISTOR, SYMPROIC, TRULANCE, ZELNORM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For all requests, the patient must have an FDA labeled indication for the requested agent.

2. For all requests, medication will not be used concomitantly with other intestinal secretagogues, selective 5-HT agonists or peripherally acting mu-opioid receptor antagonists covered by this policy

3. For patients already established on the requested product (starting on samples will not be considered as established on therapy):
i. 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)

4. For patients not established on the requested product must meet ALL of the following indication-specific criteria:
i. For chronic idiopathic constipation (CIC):
a. Documentation of weekly constipation (less than 3 spontaneous bowel movements) for at least 3 months
b. Screen for constipation-inducing medications and medical rationale provided for continuing these medications, if applicable
c. Failure, contraindication, or intolerance to 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®)
4) Lubiprostone (Amitiza®)

ii. For irritable bowel syndrome with constipation (IBS-C):
a. 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)
b. Failure, contraindication, or intolerance to 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®)
c. 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

iii. For opioid-induced constipation (OIC):
a. Patient is on chronic opioid therapy
b. Documentation of less than 3 spontaneous bowel movements per week
iv. Failure, contraindication, or intolerance of ALL of the following:
a. A stimulant laxative (e.g. senna, bisacodyl)
b. Routine laxative therapy, with a different mechanism of action than the laxative above (e.g. lactulose, Miralax®)
c. For Relistor®: Failure, contraindication, or intolerance to 1 of the following medications:
1) Naloxegol (Movantik®)
2) Lubiprostone (Amitiza®)
3) Naldemedine (Symproic®)

QUANTITY LIMIT:
Relistor:
• 8-mg syringe: 1 single use syringe per day (12 ml per 30 days)
• 12-mg syringe or vial: 1 single use syringe or vial per day (18 ml per 30 days)
• 150-mg tablet: 3 tablets per day

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

CONTINUOUS GLUCOSE MONITORS FOR PERSONAL USE

MEDICATION(S)

DEXCOM, DEXCOM G4, DEXCOM G5, DEXCOM G5-G4 SENSOR, DEXCOM G6, FREESTYLE LIBRE 10 DAY READER, FREESTYLE LIBRE 10 DAY SENSOR, FREESTYLE LIBRE 14 DAY READER, FREESTYLE LIBRE 14 DAY SENSOR, FREESTYLE LIBRE 2 READER, FREESTYLE LIBRE 2 SENSOR

COVERED USES

N/A

EXCLUSION CRITERIA

- Current pregnancy
- Gestational diabetes

REQUIRED MEDICAL INFORMATION

I. Continuous glucose monitors may be considered medically necessary and covered for the treatment of insulin-dependent diabetes when all of the following criteria are met:

A. The requested device is FDA-approved and is being used in accordance with the approved indications of use, and

B. The patient has completed a comprehensive diabetes education program, and

C. The patient has been on a program of multiple daily injections of insulin (i.e., at least 2 injections per day), and

D. Documented history of inadequate glycemic control despite compliance with frequent self-monitoring (4 or more finger sticks per day) and patient has any of the following problems controlling blood glucose level:

1. Documented hypoglycemia unawareness, or
2. Documented recurring episodes (two or more events) of clinically significant hypoglycemia (less than 54 mg/dl) or fasting hyperglycemia (greater than 150 mg/dl), or
3. Glycosylated hemoglobin level (HbA1C) greater than 7%, or
4. History of recurring, symptomatic hypoglycemia, or
5. Fasting blood sugars frequently exceeding 200 mg/dL, or
6. History of severe glycemic fluctuations, or
7. Documented need for more than 5 daily injections of insulin.

E. For the Freestyle Libre OR Libre2 device:

1. Must meet criteria outlined above (I.A-D)
2. Documented trial and failure of the preferred Dexcom G5 or G6

Replacement of Continuous Glucose Monitors

II. Upgrade or replacement of existing advanced diabetes management technology may be considered medically necessary and covered when there is documentation that one or more of the device components

meet all of the following criteria (A.-C.):
A. Are no longer functional, and
B. Are not under warranty, and
C. Cannot be repaired.
III. Upgrade or replacement of existing advanced diabetes management technology is considered not medically necessary and not covered when criterion II above is not met.
Upon approval, concurrent use of test strips will be limited to:
• Dexcom G6/Freestyle Libre: 50 test strips per 90-day supply.
• Dexcom G5: 450 test strips per 90-day supply
o An additional 50 test strips per 90 days may be approved with documentation that the patient has low blood glucose levels requiring verification at least two (2) times per week (see diabetic DME policy).

QUANTITY LIMIT:
Reader/receiver: one (1) unit per year
Sensors: one (1) pack per 30 days
Transmitters:
• G5: one (1) per 6 months
• G6: one (1) per 3 months

AGE RESTRICTION
Dexcom: May be covered for age 2 years and older
Libre: May be covered for age 18 years and older
Libre 2: May be covered for age 4 years 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

CORLANOR

MEDICATION(S)
CORLANOR

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit and inappropriate sinus tachycardia

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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 (LVEF) of 35% or less
3. Documentation that patient is currently in normal sinus rhythm with resting heart rate of at least 70 beats per minute (bpm)
4. On a maximally tolerated dose of an ACE inhibitor (e.g., lisinopril, enalapril) or ARB (e.g., losartan, valsartan), unless contraindicated or did not tolerate
5. On a maximally tolerated dose of 1 of the 3 beta-blockers proven to reduce mortality in all stable patients of heart failure with reduced left ventricular ejection fraction (carvedilol, metoprolol succinate, bisoprolol), unless contraindicated or did not tolerate
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 sinus rhythm and resting heart rate (HR) greater than 100 bpm (with a mean HR greater than 90 bpm over 24 hours) or a rapid stable symptomatic increase in resting HR greater than 25 bpm when moving from a supine to a standing position or in response to physiological stress
2. Documentation that other causes of sinus tachycardia have been ruled out (e.g. thyroid disease, drug-induced)
3. Documentation that inappropriate sinus tachycardia is causing significant functional impairment or distress, such as presyncope, headache, dyspnea

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

N/A

CRYSVITA - MEDICAL BENEFIT

MEDICATION(S)
CRYSVITA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale, patient's weight and serum phosphorus levels are required, and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary as well as patient's weight and serum phosphorus levels.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an endocrinologist or specialist experienced in the treatment of metabolic bone disorders.

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

OTHER CRITERIA
Initial authorization:
1. One of the following diagnoses:
a. Diagnosis of X-linked hypophosphatemia (XLH) supported by ONE or more of the following:
i. Confirmed PHEX mutation in the patient or a directly related family member with appropriate X-linked inheritance
ii. Elevated Serum fibroblast growth factor 23 (FGF23) level greater than 30 pg/mL
b. Clinical diagnosis of tumor-induced osteomalacia (TIO) and all of the following:
i. Associated with tumors that cannot be identified or curatively resected
ii. FGF23 level of at least 100 pg/mL, and
2. Documentation that serum phosphorus level is below the normal range for age, (use laboratory-specific reference ranges if available, otherwise, see appendix for ranges), and
3. One of the following:

a. Patient’s epiphyseal plate has NOT fused, or
b. Patient meets all of the following:
i. Patient’s epiphyseal plate has fused, and
ii. Patient is experiencing clinical signs and symptoms of disease (e.g., limited mobility, musculoskeletal pain, bone fractures), and
4. Failure of calcitriol with an oral phosphate agent, unless contraindicated or clinically significant adverse effects are experienced, and
5. Documentation of patient’s current weight and that dosing is in accordance with the United States Food and Drug Administration approved labeling

For patients established on therapy with burosumab for X-linked hypophosphatemia all of the following criteria must be met:
1. Documentation of recent serum phosphorus level and levels have normalized while on therapy, and
2. Documentation of at least one of the following responses to therapy:
a. Improvement in skeletal deformities
b. Healing of fracture or pseudofractures
c. Reduction in number of fractures/pseudofractures
d. Increase in growth velocity, and
3. Documentation of patient’s current weight and that dosing continues to be in accordance with the United States Food and Drug Administration approved labeling

For patients established on therapy with burosumab for hypophosphatemia in tumor induced osteomalacia (TIO) all of the following criteria must be met:
1. Documentation that tumor continues to be unidentifiable or unresectable
2. Documentation of recent serum phosphorus level and levels have normalized while on therapy, and
3. Documentation of at least one of the following responses to therapy:
a. Improvement in skeletal deformities
b. Healing of fracture or pseudofractures
c. Reduction in number of fractures/pseudofractures
d. Increase in growth velocity, and
4. Documentation of patient’s current weight and that dosing continues to be in accordance with the United States Food and Drug Administration approved labeling

DALIRESP

MEDICATION(S)
DALIRESP

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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% CREAM, ACYCLOVIR 5% OINTMENT, DENAVIR, SITAVIG, XERESE, ZOVIRAX 5% CREAM, ZOVIRAX 5% OINTMENT

COVERED USES
N/A

EXCLUSION CRITERIA
1. Genital or mucocutaneuos herpes simplex
2. Suppressive therapy (greater than 10 days course)
3. 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
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:
The following quantities wil be approved per rolling 365-day period
1. Sitavig® - two 50mg tablets
2. Xerese® - 10 grams
3. Denavir® - 10 grams
4. Acyclovir 5% cream (Zovirax®) - 10 grams
5. Acyclovir 5% ointment (Zovirax®) - 30 grams

Additional quantities may be approved based on medical necessity. Medications being used as suppressive therapy is not considered medically necessary.

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

DESCOVY

MEDICATION(S)
DESCOVY

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of one of the following:
1. Patient has an allergy or intolerance to emtricitabine/tenofovir disoproxil fumarate
2. Patient has presence of, or at high risk for, osteopenia or osteoporosis
3. Patient has renal impairment or a high risk for renal impairment (i.e., older age, hypertension, diabetes, nephrotoxic medications)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

DIACOMIT

MEDICATION(S)
DIACOMIT

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

DISPOSABLE INSULIN PUMPS

MEDICATION(S)
OMNIPOD DASH 5 PACK POD

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
I. Disposable insulin pumps may be considered medically necessary and covered for the treatment of insulin-dependent diabetes when one of the following criteria are met:
A. The request is for an insulin pump without a continuous glucose monitor for Type 1 diabetes
or
B. All of the following:
1. The requested device is FDA-approved and is being used in accordance with the approved indications of use, and
2. The patient has completed a comprehensive diabetes education program, and
3. The patient has been on a program of multiple daily injections of insulin (i.e., at least 2 injections per day), and
4. Documented history of inadequate glycemic control despite compliance with frequent self-monitoring (4 or more finger sticks per day) and patient has any of the following problems controlling blood glucose level:
i. Documented hypoglycemia unawareness, or
ii. Documented recurring episodes (two or more events) of clinically significant hypoglycemia (less than 54 mg/dl) or fasting hyperglycemia (greater than 150 mg/dl), or
iii. Glycosylated hemoglobin level (HbA1C) greater than 7%, or
iv. History of recurring, symptomatic hypoglycemia, or
v. Fasting blood sugars frequently exceeding 200 mg/dL, or
vi. History of severe glycemic fluctuations, or
vii. Documented need for more than 5 daily injections of insulin.

Replacement of Continuous Glucose Monitors
II. Upgrade or replacement of existing advanced diabetes management technology may be considered medically necessary and covered when there is documentation that one or more of the device components meet all of the following criteria (A.-C.):
A. Are no longer functional, and
B. Are not under warranty, and

C. Cannot be repaired.
III. Upgrade or replacement of existing advanced diabetes management technology is considered not medically necessary and not covered when criterion II above is not met.

QUANTITY LIMIT:
Omnipod Dash pods: 10 pods 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

DOPTELET, MULPLETA

MEDICATION(S)
DOPTELET, MULPLETA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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 cells/microliter
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 cells/microliter
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 cells/microliter
3. Inadequate response to at least TWO (2) of the following therapies:
a. Corticosteroids
b. Immunoglobulins
c. Splenectomy
d. Rituximab
e. Another thrombopoietin receptor agonist (e.g., eltrombopag or romiplostim)

Reauthorization:
Platelet levels demonstrating response to therapy as well as documentation that avatrombopag continues to be required to maintain a platelet count of at least 50,000 cells/microliter

QUANTITY LIMIT:
For Mulpleta®: seven (7) tablets per month

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 one (1) month for one (1) course of treatment (15 tablets of Doptelet® or seven (7) tablets of Mulpleta®)

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

OTHER CRITERIA
N/A

DPP4 INHIBITORS

MEDICATION(S)

GLYXAMBI, JANUMET, JANUMET XR, JANUVIA, JENTADUETO, JENTADUETO XR, KOMBIGLYZE XR, ONGLYZA, QTERN, STEGLUJAN, TRADJENTA, TRIJARDY XR

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

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. Trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy.
AND
2. Documented trial and failure to one (1) of the following medication classes, or intolerance/contraindication to all classes listed below (trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy):
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%,
AND
4. For non-preferred DPP-4 inhibitors (sitagliptin, linagliptin, saxagliptin): Documented trial and failure, intolerance, or contraindication to alogliptin. Trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy.

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, SYNDROS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For nausea and vomiting associated with cancer chemotherapy:
1. Documentation of trial and failure, contraindication or intolerance to one of the following formulary 5HT-3 receptor antagonist: ondansetron (available as tablet, orally disintegrating tablet, or oral solution) or granisetron tablet.
AND
2. Documentation of trial and failure, contraindication or intolerance to one of the following formulary medications unless contraindicated: promethazine, prochlorperazine, chlorpromazine, or metoclopramide.
AND
3. For coverage of dronabinol oral solution (Syndros®), documentation that the patient is unable to swallow generic dronabinol oral capsule.

For anorexia with weight loss in patients with AIDS:
1. Documentation that patient is currently taking anti-retroviral therapy
AND
2. If patient is less than 65 years of age: Documentation of trial and failure, contraindication, or intolerance to megestrol (Megace®)
AND
3. For coverage of dronabinol oral solution (Syndros®), documentation that the patient is unable to swallow generic dronabinol oral capsule.

Reauthorization requires documentation of successful response to the medication.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

Nausea/vomiting with chemotherapy: Initial authorization and reauthorization will be approved for six (6) months.

AIDS wasting: Initial authorization and reauthorization will be approved for three (3) months.

OTHER CRITERIA

N/A

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 beta 2-agonist and has been compliant to therapy in the past three (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 more than 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

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 (6) 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 three (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 more than 1.5
b. Documentation, within the last 12 months, of one (1) 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 (2) 200 mg injections) or 600 mg (two (2) 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 six (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 six (6) months. Reauthorization will be approved for one (1) year.
For asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A

DURYSTA

MEDICATION(S)
DURYSTA

COVERED USES
All FDA-Approved Indications

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The following criteria must be met:
1. The patient is not receiving re-treatment of eye(s) previously treated with Durysta®
2. Trial and failure, intolerance or contraindication to at least two ophthalmic products (either as monotherapy or as concomitant therapy) from two different pharmacological classes, one of which is an ophthalmic prostaglandin

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by an ophthalmologist

COVERAGE DURATION
Initial will be approved for 6 months. Approval will be for a one-time use in each treated eye (one implant per treated eye, a total of two implants per patient).

OTHER CRITERIA
N/A

EGRIFTA

MEDICATION(S)
EGRIFTA, EGRIFTA SV

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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 clinical improvement (e.g., decrease in waist circumference, improvement in visceral adipose tissue).

ELIDEL/PROTOPIC

MEDICATION(S)
ELIDEL, PIMECROLIMUS, PROTOPIC, TACROLIMUS 0.03% OINTMENT, TACROLIMUS 0.1% OINTMENT

COVERED USES
N/A

EXCLUSION CRITERIA
Requests for coverage for vitiligo or rosacea will not be approved due to the lack of evidence supporting their effectiveness and safety in these conditions.

REQUIRED MEDICAL INFORMATION
For Atopic Dermatitis, Psoriasis and Oral Lichen Planus
1. Documentation that conditions is causing functional impairment such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
AND
2. Documentation of one of the following
a. At least 10% of body surface area involved
OR
b. Hand, foot or mucous membrane involvement
AND
3. Documentation of trial and failure of an adequate treatment course (two (2) weeks or longer) of two (2) formulary topical corticosteroids, unless member has a contraindication to corticosteroid therapy or use would be on a part of the body where steroid application is not recommended (face, groin, axillae).

For Elidel® only:
1. Documented trial, failure, intolerance or contraindication to tacrolimus 0.1% ointment or tacrolimus 0.03% ointment

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization for three (3) months. Reauthorization for 12 months.

OTHER CRITERIA

ELZONRIS

MEDICATION(S)
ELZONRIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met:
1. Diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN)
2. Documentation that patient has a current Eastern Cooperative Oncology Group (ECOG) status of 0-1
3. Documentation that patient has a baseline serum albumin level of at least 3.2 g/dL
4. Documentation that patient has adequate cardiac function, defined as LVEF of at least 50% and none of the following:
a. Uncontrolled or any NYHA Class 3 or 4 congestive heart failure
b. Uncontrolled angina
c. History of myocardial infarction or stroke within 6 months of initiating therapy
d. Uncontrolled hypertension
e. Clinically significant arrhythmias not controlled by medication
Reauthorization requires documentation of positive response to therapy, such as a lack of disease progression.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial and reauthorization will be approved for 6 months

OTHER CRITERIA
N/A

EMFLAZA

MEDICATION(S)
EMFLAZA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient’s 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
2 years and up

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with a provider that specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders

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

OTHER CRITERIA
Initial authorization:
1. The patient has a diagnosis of Duchenne Muscular Dystrophy (prescriber must provide genetic test to confirm diagnosis)
2. Documentation of one of the following:
a. The patient has tried prednisone for at least 6 months and has experienced one of the following clinically significant adverse events: cushingoid appearance, central (truncal obesity), weight gain of at least 10% body weight over a 6-month period or diabetes and/or hypertension that is difficult to manage according to the prescribing physician
OR
b. The patient has tried prednisone and has experienced psychiatric/behavioral issues (eg, abnormal behavior, aggression, irritability)

i. The psychiatric/behavioral issues persisted beyond the first 6 weeks of treatment with prednisone
AND
ii. A change in timing of prednisone administration (eg, afternoon or evening) has been attempted but was unsuccessful in resolving issues
3. The dose requested is within FDA labeled dosing based on the patient's weight (patient's weight must be provided) AND dose is given in most cost effective manner (e.g., rounding to appropriate tablet strength or use of suspension)

Re-authorization:
1. Documentation of clinical benefit from therapy, such as improvement or stabilization of muscle strength or pulmonary function
2. The dose requested is within FDA labeled dosing based on the patient's weight (updated weight must be provided) AND dose is given in most cost effective manner (e.g., rounding to appropriate tablet strength or use of suspension)

QUANTITY LIMIT:
6 mg tablet: 2 tablets per day,
18 mg tablet: 1 tablet per day.

ENSPRYNG

MEDICATION(S)
ENSPRYNG

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:
1. Diagnosis of neuromyelitis optica spectrum disorder as defined as the following:
a. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions)
AND
b. Anti-AQP4 antibody positive
2. Documentation that other alternative diagnoses have been excluded (i.e. Multiple Sclerosis)
3. Trial and failure, intolerance or contraindication to rituximab
4. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
5. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for Neuromyelitis Optica Spectrum Disorder (NMOSD):
1. Documentation of positive clinical response to therapy
2. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
3. Dose and frequency is in accordance with FDA-approved labeling

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by a neurologist

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

OTHER CRITERIA

N/A

ENSTILAR/TACLONEX/TACLONEX SCALP

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

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For calcipotriene & betamethasone ointment (Taclonex®) and calcipotriene & betamethasone ointment topical suspension (Taclonex® Scalp):
1. Documentation of trial and failure of calcipotriene cream or solution and betamethasone (as separate products) simultaneously OR inability (other than convenience or non-compliance) to use two separate medications

For calcipotriene & betamethasone aerosol foam (Enstilar®):
1. Documentation of trial and failure of calcipotriene cream or solution and betamethasone (as separate products) simultaneously OR inability (other than convenience or non-compliance) to use two separate medications
AND
Documentation of trial and failure of calcipotriene & betamethasone ointment (Taclonex®) or calcipotriene & betamethasone ointment topical suspension (Taclonex® Scalp)

For Medicaid ONLY for all products:
1. Documentation that condition is causing functional impairment such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
AND
2. Documentation of one of the following:
a. At least 10% of body surface area involved
OR
b. Hand, foot or mucous membrane involvement

AGE RESTRICTION
Enstilar: 12 years of age and older
Taclonex: 12 years of age and older

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

ENZYME REPLACEMENT THERAPY

MEDICATION(S)

ALDURAZYME, CEREZYME, ELAPRASE, ELELYSO, FABRAZYME, KANUMA, LUMIZYME, MEPSEVII, NAGLAZYME, VIMIZIM, VPRIV

COVERED USES

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial authorization and any dose increases will require a current (within 6 months) 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

- Aldurazyme®: N/A
- Cerezyme®: N/A
- Elaprase®: The safety and efficacy of Elaprase® have not been established in pediatric patients less than 16 months of age
- Elelyso®: The safety and efficacy of Elelyso™ have not been established in pediatric patients less than 4 years of age
- Fabrazyme®: Safety and efficacy not established in pediatric patients under 8 years of age
- Kanuma®: N/A
- Lumizyme®: N/A
- Mepsevii®: N/A
- Naglazyme®: N/A
- Vimizim®: The safety and effectiveness of Vimizim® have not been established in pediatric patients less than 5 years of age
- Vpriv®: The safety and efficacy of Vpriv® have not been established in pediatric patients less than 4 years of age

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a Hepatologist, Endocrinologist, Medical Geneticist, Cardiologist, Pulmonologist, or Bone and Mineral specialist

COVERAGE DURATION

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

OTHER CRITERIA

Documentation of FDA-labeled indication (Appendix) for the following products:

- Aldurazyme® (laronidase)
- Cerezyme® (imiglucerase)
- Elaprase® (idursulfase)
- Elelyso® (taliglucerase alfa)
- Fabrazyme® (agalsidase beta)
- Kanuma® (sebelipase alfa)
- Lumizyme® (alglucosidase alfa)
- Mepsevii® (vestronidase alfa-vjbk)
- Naglazyme® (galsulfase)
- Vimizim® (elosulfase alfa)
- Vpriv® (velaglucerase alfa)

REAUTHORIZATION:

Documentation of successful response to therapy (e.g., disease stability or improvement in symptoms).

QUANTITY LIMIT:

Initial dose approval will be based on patient’s current weight (Appendix). Increases in dose will require new authorization with patient’s weight and relevant chart notes

EPIDIOLEX

MEDICATION(S)
EPIDIOLEX

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

ERYTHROPOIESIS STIMULATING AGENTS (ESAS)

MEDICATION(S)

ARANESP, EPOGEN, PROCRIT, RETACRIT

COVERED USES

N/A

EXCLUSION CRITERIA

• Patients with uncontrolled hypertension
• Anemia induced from hepatitis C therapy

REQUIRED MEDICAL INFORMATION

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 more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 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 more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 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 4200mg/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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

ESBRIET/OFEV

MEDICATION(S)
ESBRIET, OFEV

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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, dyspnea).

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 (two (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
AND
3. For Medicaid only:
a. Documentation that conditions is causing functional impairment such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
AND
b. Documentation of one of the following
i. At least 10% of body surface area involved
OR
ii. Hand, foot or mucous membrane involvement

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

EVENITY

MEDICATION(S)
EVENITY, EVENITY (2 SYRINGES)

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
Myocardial infarction or stroke within the preceding year, hypocalcemia

REQUIRED MEDICAL INFORMATION
For treatment or prevention of osteoporosis: 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 1 year, ensuring the total duration of Evenity® therapy does not exceed 1 year of total therapy duration.

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)

EVRYSDI

MEDICATION(S)
EVRYSDI

COVERED USES
N/A

EXCLUSION CRITERIA
1. Use in combination with Spinraza (nusinersen) therapy
2. Concomitant use with, or following, gene therapy for SMA (e.g., onasemnogene abeparvovec)

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. The patient has a diagnosis, confirmed by genetic testing, of Spinal Muscular Atrophy (SMA) type 1, 2, or 3
2. Patient does not require invasive ventilation or tracheostomy
3. Baseline assessment with an age appropriate tool that establishes baseline motor ability must be submitted (e.g., HINE-2, HFSME, CHOP-INTEND, MFM-32)
4. Requested dose is within FDA labeling

Reauthorization:
1. Documentation of response to therapy, such as a clinically meaningful improvement in motor function, disease stabilization or a reduction in normal motor decline (e.g., stabilization or improvement in motor function test scores performed at baseline)
2. Requested dose is within FDA labeling

AGE RESTRICTION
May be approved for patients aged two (2) months and older

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

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

OTHER CRITERIA
N/A

EVZIO

MEDICATION(S)
EVZIO

COVERED USES
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Medical justification supported by chart note documenting why the patient’s caregiver is unable to use all of the following:
1. Injectable, generic naloxone vial or syringe (e.g., poor dexterity, poor eyesight, or infectious disease (HIV, Hepatitis C) requiring limiting risk of needle stick)
AND
2. Narcan® nasal spray
AND
3. Generic naloxone auto-injector

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for six months

OTHER CRITERIA
N/A

EXON-SKIPPING THERAPIES FOR DUCHENNE MUSCULAR DYSTROPHY

MEDICATION(S)
EXONDYS-51, VILTEPSO, VYONDYS-53

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
N/A

OTHER CRITERIA
Eteplirsen (Exondys® 51), golodirsen (Vyondys® 53) and viltolarsen (Viltepso®) are not considered medically necessary and will not be covered due to the lack of clinical evidence of improved outcomes and safety.

EXTAVIA

MEDICATION(S)
EXTAVIA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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)

ABSTRAL, ACTIQ, FENTANYL CIT 100 MCG BUCCAL TB, FENTANYL CIT 200 MCG BUCCAL TB, FENTANYL CIT 400 MCG BUCCAL TB, FENTANYL CIT 600 MCG BUCCAL TB, FENTANYL CIT 800 MCG BUCCAL TB, 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, FENTORA, LAZANDA, SUBSYS

COVERED USES

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

FINTEPLA

MEDICATION(S)
FINTEPLA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
Concomitant use of, or within 14 days of administration of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome

REQUIRED MEDICAL INFORMATION
Initial Authorization:
1. Documentation that the patient has seizures associated with Dravet syndrome (DS)
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. Clobazam
c. Levetiracetam
d. Topiramate
e. Stiripentol
f. Diazepam

Reauthorization:
Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an epilepsy specialist or pediatric neurologist.

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

OTHER CRITERIA
N/A

FORTEO

MEDICATION(S)
FORTEO, TERIPARATIDE

COVERED USES
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit.

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
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

GAMIFANT

MEDICATION(S)
GAMIFANT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initiation Criteria:
1. Diagnosis of primary HLH based on a molecular diagnosis OR family history consistent with primary HLH OR 5 out of the following 8 criteria fulfilled:
a. Fever
b. Splenomegaly
c. Cytopenias affecting 2 of 3 lineages in the peripheral blood: hemoglobin less than 9 g/dL, platelets less than 100 x 109/L, neutrophils less than 1 x 109/L
d. Hypertriglyceridemia (fasting triglycerides greater than 3 mmol/L or equal or greater than 265 mg/dL) and/or hypofibrinogenemia (equal or less than 1.5 g/L)
e. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
f. Low or absent NK-cell activity
g. Ferritin equal or greater than 500 mcg/L
h. Soluble CD 25 equal or greater than 2400 U/mL
2. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy (corticosteroids, methotrexate, cyclosporine A, etoposide, anti-thymocyte globulin) based on one of the following criteria:
a. Having not responded or not achieved a satisfactory response
b. Having not maintained a satisfactory response to conventional HLH therapy
c. Intolerance to conventional HLH treatments
3. Patient is a candidate for stem cell transplant and emapalumab is being used as part of the induction or maintenance phase for stem cell transplant and will be discontinued at the initiation of conditioning for stem cell transplant
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling
5. Documentation that patient currently has no active infection (e.g. mycobacteria and Histoplasma Capsulatum)

Reauthorization Criteria:

1. Patient continues to be a candidate for stem cell transplant
2. Documentation of disease improvement such as:
a. Complete response defined as normalization of all HLH abnormalities (i.e. no fever, no splenomegaly, neutrophils more than 1x109/L, platelets more than 100x109/L, ferritin less than 2,000 µg/L, fibrinogen more than 1.50g/L, D-dimer less than 500 µg/L, normal CNS symptoms, no worsening of sCD25 more than 2-fold baseline)
b. Partial response defined as normalization of more than or equal to 3 HLH abnormalities
c. HLH improvement defined as more than or equal 3 HLH abnormalities improved by at least 50% from baseline
3. Documentation that patient is being monitored for serious infections (such as tuberculosis, adenovirus, EBV, and CMV)
4. Documentation that dose does not exceed max FDA approved dosing of 10 mg/kg per dose for two doses per week

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization approved for 3 months, reauthorization for 1 month

OTHER CRITERIA
N/A

GATTEX

MEDICATION(S)
GATTEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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

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
N/A

GIVLAARI

MEDICATION(S)
GIVLAARI

COVERED USES
N/A

EXCLUSION CRITERIA
Use post liver transplant

REQUIRED MEDICAL INFORMATION
For initial authorization, all of the following criteria must be met:
1. Confirmed diagnosis of acute hepatic porphyria [i.e., acute intermittent porphyria, hereditary corproporhyria, variegate porphyria, aminolevulinic acid (ALA) dehydratase deficient porphyria]
AND
2. One of the following:
a. Active disease defined as two (2) documented porphyria attacks within the past six (6) months which required either hospitalization, urgent care visit, or intravenous hemin administration, or
b. Patient is currently receiving treatment with prophylactic hemin to prevent porphyria attacks
3. Documentation that patient will not receive concomitant prophylactic hemin treatment while on therapy with givosiran therapy
4. Documentation that patient's dosing is in accordance with FDA labeling (patient's current weight must be included in documentation) and is subject to audit

Reauthorization requires documentation of one of the following:
1. Reduction in the number or severity of porphyria attacks
2. Reduction in number of hospitalizations due to acute porphyria attacks
3. Decreased hemin administration from baseline

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

N/A

GNRH ANTAGONISTS

MEDICATION(S)
ORIAHNN, ORILISSA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
1. Patient has osteoporosis or severe hepatic impairment
2. Undiagnosed abnormal uterine bleeding

REQUIRED MEDICAL INFORMATION
For endometriosis (Orilissa® only):
Initial Authorization
1. Documentation that patient has moderate to severe pain associated with endometriosis, AND
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, AND
2. Documentation of a positive response to therapy (e.g., reduction in pain)

For management of heavy menstrual bleeding associated with uterine leiomyomas/fibroids (Oriahnn™ only):
Initial Authorization
1. Documentation of confirmed diagnosis of uterine fibroids (e.g. ultrasound), AND
2. Documentation of heavy menstrual bleeding, AND
3. Documentation that patient has trial and failure of, intolerance to, or contraindication to hormonal contraceptives

Reauthorization:
1. Total treatment duration will not exceed 24 months, AND
2. Documentation of a positive response to therapy (e.g., reduction in bleeding)

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.

Oriahnn™: Initial authorization for 6 months. Reauthorization for up to 18 months. No reauthorization beyond 24 months

OTHER CRITERIA

N/A

GONADOTROPIN RELEASING HORMONE AGONISTS

MEDICATION(S)
ELIGARD, FENSOLVI, LEUPROLIDE 2WK 1 MG/0.2 ML KIT, LEUPROLIDE 2WK 14 MG/2.8 ML KT, LUPANETA PACK, LUPRON DEPOT, LUPRON DEPOT-PED, SUPPRELIN LA, SYNAREL, TRIPTODUR, VANTAS, ZOLADEX

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 six (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 eight (8) years and under for females or nine (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 (1) 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 three (3) months (NO reauthorization)
Uterine leiomyomata (fibroids): Authorization will be approved for four (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 six (6) months and no reauthorization
CPP: Authorization/reauthorization will be approved for up to one (1) year
GID: Authorization/reauthorization will be approved for up to one (1) year
Endometrial Thinning/Dysfunctional Uterine Bleeding: Initial authorization for two (2) months. No reauthorization.
Oncological Indications: Authorization/reauthorization will be approved for one (1) year
In vitro fertilization: Authorization/reauthorization will be approved for one (1) year

OTHER CRITERIA
N/A

HEMLIBRA - MEDICAL BENEFIT

MEDICATION(S)
HEMLIBRA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Use is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
AND
2. Diagnosis of hemophilia A (congenital factor VIII deficiency) and documentation of ANY of the following:
a. Factor VIII inhibitors (defined as at least 5 Bethesda units per milliliter)
b. Severe hemophilia (defined as pre-treatment factor VIII level less than 1%)
c. Moderate hemophilia (defined as pre-treatment factor VIII level of 1% to less than 5%) or mild hemophilia (defined as pre-treatment factor VIII level of 5% to less than 40%) with:
i. One (1) or more spontaneous episodes of bleeding into the central nervous system, large joints (ankles, knees, hips, elbows, shoulders) or other serious, life-threatening bleed

When the above criteria are met, Hemlibra® (emicizumab-kxwh) will be approved for a loading dose of 3 mg/kg once weekly for four (4) weeks, followed by any of the three (3) maintenance dosing regimens below:
• 1.5 mg/kg once weekly
• 3 mg/kg every 2 weeks
• 6 mg/kg every 4 weeks

Reauthorization criteria: Documentation of positive clinical response to emicizumab therapy (e.g. reduction in the number/severity of bleeds)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
To be prescribed by, or in consultation with a hematologist.

COVERAGE DURATION
Initial authorization: six (6) months
Reauthorization: 12 months

OTHER CRITERIA

N/A

HEPATITIS C- DIRECT ACTING ANTIVIRALS

MEDICATION(S)

EPCLUSA, HARVONI, LEDIPASVIR-SOFOSBUVIR, MAVYRET, SOFOSBUVIR-VELPATASVIR, SOVALDI, VIEKIRA PAK, VOSEVI, ZEPATIER

COVERED USES

N/A

EXCLUSION CRITERIA

All regimens containing a NS3/4a protease inhibitor (e.g. Mavyret, Vosevi, Zepatier and Viekira Pak) are not covered in patients with moderate to severe hepatic impairment (Child-Pugh B or C)

REQUIRED MEDICAL INFORMATION

1. Documentation of confirmed diagnosis of chronic hepatitis C (HVC) infection (B18.2)
AND
2. Expected survival from non-HCV-associated morbidities more than one (1) year
AND
3. Documentation that ALL of the following pre-treatment testing has been performed:
a. Genotype testing in past three (3) years is only required for the following population:
i. Patients with cirrhosis
ii. Patients with any prior treatment experience,
iii. For regimens which are not pan-genotypic (e.g. Harvoni, Zepatier)
b. Current HBV status of patient
Note: Direct-acting antiviral agents can re-activate hepatitis B in some patients. Patients with history of HBV should be monitored carefully during and after treatment for flare-up of hepatitis. Prior to treatment with a DAA, all patients should be tested for HBsAG, HBsAb, and HBcAB status.
c. History of previous HCV treatment and outcome. Retreatment after failure of a DAA due to noncompliance or lost to follow-up will be reviewed on a case-by-case basis.
d. Cirrhosis status as clinically determined (e.g., clinical, laboratory, or radiologic evidence)
AND
4. Attestations that the patient and provider will comply with all case management interventions to promote the best possible outcome for the patient and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load. Case management includes assessment of treatment barriers and offer of patient support to mitigate potential barriers to regimen adherence as well as facilitation of SVR12 evaluation to assess treatment success.
AND
5. For coverage of non-preferred regimen, the prescriber must submit medical rationale in support of the use of non-preferred drug(s).

AND
6. For coverage of elbasvir/grazoprevir (Zepatier) in genotype 1a, NS5A resistance testing is required to detect any potential resistant variant.

QUANTITY LIMIT:
28 day-supply per dispense

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For patients who have complication of 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
Coverage duration will be based on genotype and regimen.

OTHER CRITERIA
N/A

HETLIOZ

MEDICATION(S)
HETLIOZ

COVERED USES
N/A

EXCLUSION CRITERIA
Sleep disorders other than Non-24 and SMS.

REQUIRED MEDICAL INFORMATION
For Non-24-Hour Sleep-Wake Disorder (Non-24):
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.

For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS):
All of the following criteria must be met:
1. Documented diagnosis of SMS, as characterized by:
a. Confirmation of the deletion or mutations of retinoic acid-induced 1 (RAI1) gene
2. Documented sleep study to exclude other sleep disorders
3. Documentation of at least one of the following:
a. difficulties falling asleep
b. shortened sleep cycles
c. frequent and prolonged nocturnal awakenings

d. excessive daytime sleepiness
e. daytime napping
4. Documented trail and failure or contraindication of melatonin dosed in the morning or daytime administration of acebutolol combined with melatonin dosed at bedtime.

Reauthorization Criteria:
Documentation of improvement in sleep quality or total sleep time.

QUANTITY LIMIT:
Hetlioz® capsules: Limited to 30 capsules per 30 days
Hetlioz® LQ oral suspension: Limited to 150mL per 30 days

AGE RESTRICTION
Non-24: 18 years or older for capsules
SMS: 3-15 years old for suspension and 16 years or older for capsules

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
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

Coverage for Medicaid 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.

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

COVERED USES
Infantile spasms

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 PEDIATRICS

MEDICATION(S)
GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SAIZEN-SAIZENPREP, SEROSTIM, ZOMACTON, ZORBTIVE

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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)

CINQAIR, FASENRA, FASENRA PEN, NUCALA

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 (1) 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 three (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 (1) 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 (2) 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 two (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 three (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

For Hyperesosinophilic Syndrome (HES)
1. Request is for Nucala®
2. Document of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma
3. Blood eosinophil count of 1,000 cells/mcL or higher for at least six (6) months
4. Documentation of use of HES therapy including one of the following in the past for the past 12 months:
a. chronic or episodic oral corticosteroids (OCS)
b. immunosuppressive therapy
c. cytotoxic therapy
5. Documentation of at least two HES flares within the past 12 months (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)

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: one (1) per 28 days (quantities of three (3) per 28 days are approvable for EGPA and HES)
Fasenra® Pen: one (1) per 56 days (quantities of one (1) per 28 days will be allowed for three (3) month for initial loading dose)

AGE RESTRICTION
Nucala®: Approved for six (6) years of age or older for eosinophilic asthma, approved for 18 years of age and older for EGPA and approved for 12 years of age and older for HES
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

For hypereosinophilic syndrome (HES): must be prescribed by or in consultation with hematologist, immunologist, pulmonologist, cardiologist, or neurologist.

COVERAGE DURATION

Initial authorization will be approved for six (6) months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

IMMUNE GAMMA GLOBULIN (IGG)

MEDICATION(S)
ASCENIV, BIVIGAM, CUTAQUIG, CUVITRU, FLEBOGAMMA DIF, GAMASTAN, GAMASTAN S-D, GAMMAGARD LIQUID, GAMMAGARD S-D, GAMMAKED, GAMMAPLEX, GAMUNEX-C, HIZENTRA, HYQVIA, OCTAGAM, PANZYGA, PRIVIGEN, XEMBIFY

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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. 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
1. The patient has one of the following:
a. The patient has a total IgG less than 200 mg/dL at baseline prior to immune globulin therapy
b. The patient has abnormal Bruton tyrosine kinase (BTK) gene or absence of BTK protein
c. The patient has an absence of B lymphocytes
d. The patient meets all of the following:
i. One of the following:
1. The patient has selective IgG subclass deficiency [Defined as deficiency of 1 or more IgG subclasses

(e.g., IgG1, IgG2, IgG3, or IgG4) more than 2 standard deviations (SD) below age-specific mean, assessed on 2 separate occasions during infection free period
2. The patient has specific antibody deficiency (SAD) with normal levels of both immunoglobulin and total IgG subclasses
3. The patient has hypogammaglobulinemia (defined as total IgG less than 700 mg/dL OR more than 2 SDs below mean for the patient's age at baseline prior to immune globulin therapy)
ii. The patient has a lack of response or inability to mount an adequate response to protein and/or polysaccharide antigens (e.g., inability to make IgG antibody against either diphtheria and tetanus toxoids, or pneumococcal polysaccharide vaccine, or both)
iii. The patient has evidence of recurrent, persistent, severe, difficult-to-treat infections (e.g., recurring otitis media, bronchiectasis, recurrent infections requiring IV antibiotics) despite aggressive prophylactic management and treatment with antibiotics

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 700 mg/dL OR more than 2 standard deviations below mean for the patient's age
OR
2. History of recurrent, severe bacterial infections requiring antibiotics and/or hospitalization

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 than 100,000
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. Documentation of one of the following:
a. Therapy is requested for use within 100 days after transplantation (transplantation date must be documented)
OR

b. Documentation that patient has an IgG less than 400 mg/dl with a history of recurrent infections

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).

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.

OTHER CRITERIA
N/A

INCRELEX

MEDICATION(S)
INCRELEX

COVERED USES
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit.

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 - MEDICAL BENEFIT

MEDICATION(S)

CHORIONIC GONAD 10,000 UNIT VL, CRINONE, ENDOMETRIN, FOLLISTIM AQ, GONAL-F, GONAL-F RFF, GONAL-F RFF REDI-JECT, MENOPUR, NOVAREL, OVIDREL, PREGNYL

COVERED USES

Infertility subject to benefit limitations, maintenance of pregnancy, and cryptorchidism subject to criteria below.

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)

ABRAXANE, ACTIMMUNE, ADCETRIS, ALIQOPA, ALKERAN 50 MG VIAL, ARRANON, ARZERRA, ASPARLAS, AVASTIN, AZACITIDINE, AZEDRA DOSIMETRIC, AZEDRA THERAPEUTIC, BAVENCIO, BELEODAQ, BELRAPZO, BENDAMUSTINE HCL, BENDEKA, BESPONSA, BLENREP, BLINCYTO, BORTEZOMIB, CYRAMZA, DACOGEN, DANYELZA, DARZALEX, DARZALEX FASPRO, DECITABINE, EMPLICITI, ENHERTU, ERBITUX, FASLODEX, FOLOTYN, FULVESTRANT, HALAVEN, HERCEPTIN, HERCEPTIN HYLECTA, HERZUMA, IMFINZI, IMLYGIC, ISTODAX, IXEMPRA, JEVTANA, KADCYLA, KANJINTI, KEYTRUDA, KYPROLIS, LARTRUVO, LIBTAYO, LUMOXITI, LUTATHERA, MELPHALAN HCL, MONJUVI, MVASI, OGIVRI, ONIVYDE, ONTRUZANT, OPDIVO, PADCEV, PERJETA, PHESGO, POLIVY, PORTRAZZA, POTELIGEO, ROMIDEPSIN, SARCLISA, SYLATRON, SYNRIBO, TECENTRIQ, TEMODAR 100 MG VIAL, TEMSIROLIMUS, TORISEL, TRAZIMERA, TREANDA, TRODELVY, VECTIBIX, VELCADE, VIDAZA, VYXEOS, XOFIGO, YERVOY, YONDELIS, ZALTRAP, ZEPZELCA, ZIRABEV

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

For patients established on therapy: 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

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

OTHER CRITERIA

N/A

INSOMNIA AGENTS-MEDICAID

MEDICATION(S)

AMBIEN, AMBIEN CR, BELSOMRA, DAYVIGO, DOXEPIN HCL 3 MG TABLET, DOXEPIN HCL 6 MG TABLET, ESZOPICLONE, FLURAZEPAM HCL, HALCION, INTERMEZZO, LUNESTA, RAMELTEON, RESTORIL, ROZEREM, SILENOR, TEMAZEPAM, TRIAZOLAM, ZALEPLON, ZOLPIDEM TARTRATE, ZOLPIDEM TARTRATE ER

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For patients not established on the requested sedative:

1. Patient is being treated under palliative care services with a life-threatening illness or severe advanced illness (i.e. cancer), OR

2. Patient is being treated for a funded condition that cannot be controlled with standard treatments and meets all of the following:

a. Patient is currently being treated for a funded co-morbid condition as indicated by one of the following:

i. Obstructive sleep apnea: CPAP

ii. Depression, anxiety, panic disorder, bipolar disorder: antidepressant, antipsychotic, or other appropriate mental health drug

iii. Other funded condition which is being exacerbated by insomnia, for which there is evidence of medical benefit of sedatives, and is not currently controlled by standard treatments

b. Patient has not been treated with another non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days. If patient has been treated with a sedative in past 30 days, this criteria may be waived if this is a switch in sedative therapy due to intolerance, allergy, or ineffectiveness of prior sedative and notes clearly indicate that the other sedative has been discontinued

c. Patient has had a documented trial of Cognitive Behavior Therapy (CBT) which must include education on sleep hygiene improvements

d. For non-preferred drugs: Trial and failure, contraindication, or intolerance to zolpidem AND eszopiclone

For patients established on the requested sedative:

Patient has a need for continued treatment with a sedative, meeting one of the following:

1. Patient is being treated under palliative care services with a life-threatening illness or severe advanced illness (i.e. cancer), OR

2. Patient is being treated for a funded condition that cannot be controlled with standard treatments and

meets all of the following:
a. Patient is currently being treated for a funded co-morbid condition as indicated by one of the following:
i. Obstructive sleep apnea: CPAP
ii. Depression, anxiety, panic disorder, bipolar disorder: antidepressant, antipsychotic, or other appropriate mental health drug
iii. Other funded condition which is being exacerbated by insomnia, for which there is evidence of medical benefit of sedatives, and is not currently controlled by standard treatments
b. For non-preferred drugs: Trial and failure, contraindication, or intolerance to zolpidem AND eszopiclone
c. Patient has had a positive response to therapy without side effects and noted improvement in the funded condition
d. If patient is taking a non-benzodiazepine sedative, benzodiazepine, or opioid in combination with the requested sedative the following must be met:
i. Rationale must be provided addressing need for continuing sedative therapy despite potential risks, AND
ii. Documentation that the sedative has been titrated down from the initial authorization OR documentation of a specific tapering plan OR medical rationale for not attempting a taper at this time

QUANTITY LIMIT:
15 tablets per 30 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
• Palliative care services: Initial and reauthorization will be approved up to 1 year.
• Insomnia for other conditions: Initial authorization will be approved up to 2 months. Reauthorization will be approved up to 6 months.

OTHER CRITERIA
N/A

INTERLEUKIN – 1 INHIBITORS - ARCALYST, ILARIS

MEDICATION(S)
ARCALYST, ILARIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) confirmed by:
1. Laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family (NLR) pyrin domain containing 3) or CIAS1 (Cold-Induced Auto-inflammatory Syndrome-1),
AND
2. Classic symptoms associated with Familial Cold Auto-Inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) – recurrent intermittent fever and rash typically associated with natural or artificial cold

For Arcalyst® only:
1. Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) confirmed by laboratory evidence of genetic mutation in IL1RN (encodes for interleukin-1 receptor antagonist)
2. Current inflammatory remission of DIRA
3. Weight of at least 10 kg

For Ilaris® only:
For Familial Mediterranean Fever (FMF), and all the following:
1. Documented trial and failure, contraindication or intolerance to colchicine,
AND
2. Classic symptoms associated with FMF (febrile episodes, pain in the abdomen, chest, or arthritis of large joints).

Diagnosis of Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) confirmed by:
1. Laboratory evidence of genetic mutation MVK (mevalonate kinase),
AND
2. Classic symptoms associated with HIDs (abdominal pain, lymphadenopathy, aphthous ulcers).

Diagnosis of Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) confirmed by:
1. Laboratory evidence of genetic mutation TNFRSF1A (tumor necrosis factor receptor super family),
AND
2. Classic symptoms associated with TRAPs (abdominal pain, skin rash, musculoskeletal pain, eye manifestations).

Diagnosis of Active Still's Disease including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease:
1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
AND
2. Documentation of trial, failure, intolerance, or contraindication to both etanercept (Enbrel®) and adalimumab (Humira®)

Reauthorization: Documentation submitted of improvement of symptoms (such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis for CAPS)

AGE RESTRICTION
Arcalyst®: may be covered for patients aged 12 years and older with CAPS (which includes FCAS, MWS).

Ilaris® may be covered for patients aged 4 years of age and older in patients with CAPS (which includes FCAS, MWS), Periodic Fever Syndromes including TRAPS, HIDS/MKD, and FMF

Ilaris® may be covered for patients aged 2 years of age and older in patients with Active Systemic Juvenile Idiopathic Arthritis and Adult Onset Still's Disease (AOSD)

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

INTRANASAL ALLERGY MEDICATIONS

MEDICATION(S)

24 HOUR NASAL ALLERGY, ALLER-CORT, AZELASTINE 0.1% (137 MCG) SPRY, BECONASE AQ, CHILDREN'S FLONASE SENSIMIST, CHILDREN'S NASACORT, CROMOLYN SODIUM NASAL SPRAY, FLONASE SENSIMIST, FLUNISOLIDE 0.025% SPRAY, IPRATROPIUM 0.03% SPRAY, IPRATROPIUM 0.06% SPRAY, MOMETASONE FUROATE 50 MCG SPRY, NASACORT, NASAL ALLERGY, NASAL ALLERGY SPRAY, NASALCROM, NASONEX, OLOPATADINE 665 MCG NASAL SPRY, OMNARIS, PATANASE, QNASL, QNASL CHILDREN, TRIAMCINOLONE 55 MCG NASAL SPR, ZETONNA

COVERED USES

Allergic rhinitis when a co-morbidity affected by difficult breathing exists, as outlined in criteria below.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Coverage for Medicaid 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 allergic rhinitis:
1. The requested medication is an intranasal corticosteroid (use is considered unfunded)
2. Confirmed diagnosis of allergic or non-allergic rhinitis
3. Confirmed diagnosis of one of the following co-morbidities:
a. Asthma or reactive airway within the past year
i. If patient has used an inhaled corticosteroid controller medication for asthma within the past 90 days, intranasal corticosteroid therapy will not be covered (asthma-related outcomes are not improved by the addition of an intranasal corticosteroid to an orally inhaled corticosteroid)
b. Chronic sinusitis
c. Acute sinusitis
d. Sleep apnea
AND
4. Documented trial and failure*, intolerance or contraindication to fluticasone propionate nasal spray (Flonase®), which is available without prior authorization. *Trial and failure is defined as at least two weeks of therapy.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Acute sinusitis comorbidity: Authorization will be approved for one (1) month
All other indications: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA

N/A

ISTURISA, SIGNIFOR

MEDICATION(S)
ISTURISA, SIGNIFOR

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

JUXTAPID

MEDICATION(S)
JUXTAPID

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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 more 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.

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

N/A

KETOCONAZOLE (NIZORAL TABLETS)

MEDICATION(S)
KETOCONAZOLE 200 MG TABLET

COVERED USES
N/A

EXCLUSION CRITERIA
Candida, tinea versicolor, or dermatophyte infections

REQUIRED MEDICAL INFORMATION
1. Treatment is for blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis
AND
2. Patient has failed or are intolerant to other therapies for the respective indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an infectious disease specialist.

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

OTHER CRITERIA

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

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit. May also be covered for migraine subject to criteria.

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)

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

KEVEYIS

MEDICATION(S)
KEVEYIS

COVERED USES
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
Concomitant high-dose aspirin.

REQUIRED MEDICAL INFORMATION
1. Documented diagnosis of a periodic paralysis (PP) and/or related variants
AND
2. Documentation of at least a three-month history of distinct regular episodes of weakness, defined as an average frequency of at least one episode per week, but less than three episodes daily
AND
3. Documentation that lifestyle changes (such as increase in exercise, for hyperkalemic PP: high carbohydrate meals and avoiding cold exposure and potassium rich foods, for hypokalemic PP: low sodium, low carbohydrate diet, potassium supplements) have been attempted to identify and avoid potential triggers.
AND
4. Inadequate treatment response, intolerance, or contraindication to acetazolamide (exception may be made for members with sodium voltage gated channel alpha subunit 4 [SCN4A] mutation).

Reauthorization requires documented improvement in severity and frequency of periodic paralysis attacks.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist or endocrinologist

COVERAGE DURATION
Initial authorization 3 months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
N/A

KORLYM

MEDICATION(S)
KORLYM

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
Current pregnancy

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 endocrinologist.

COVERAGE DURATION
Initial authorization for 6 months. Reauthorization for 12 months.

OTHER CRITERIA
1. Documentation that the patient has hyperglycemia secondary to endogenous Cushing's Syndrome (defined as hypercortisolism that is not a result of chronic administration of high dose glucocorticoids) AND
2. Documentation that the patient has type 2 diabetes mellitus or glucose intolerance AND
3. Documentation that the patient has failed surgery or is not a candidate for surgery

Reauthorization: Documentation that the patient has improved or stable glucose tolerance

KOSELUGO

MEDICATION(S)
KOSELUGO

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

KRYSTEXXA - MEDICAL BENEFIT

MEDICATION(S)
KRYSTEXXA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial therapy, all of the following criteria must be met:
1) Documentation of frequent and disabling gout flares with history of at least three documented disabling flares in the past 18 months
AND
2) Documented trial, failure, contraindication or intolerance to the maximum medically appropriate dose of allopurinol.
AND
3) Documented trial, failure, contraindication or intolerance to probenecid.

Note: an adequate trial and failure is at least one month of continuous therapy

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for up to six months of intermittent long-term therapy.

OTHER CRITERIA
N/A

KUVAN

MEDICATION(S)
KUVAN, SAPROPTERIN DIHYDROCHLORIDE

COVERED USES
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit.

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

LEMTRADA - MEDICAL BENEFIT

MEDICATION(S)
LEMTRADA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
• In combination with other disease modifying therapy indicated for the treatment of MS
• For treatment beyond two years or beyond two treatment courses.

REQUIRED MEDICAL INFORMATION
1. Documentation of confirmed diagnosis of relapsing form of multiple sclerosis or active secondary progressive disease
AND
2. Documentation of active disease (e.g. patients with frequent attacks or who are rapidly progressing in disability) after an adequate trial to ocrelizumab (Ocrevus®)
AND
3. Documentation of active disease after at least one additional of the following disease modifying therapies, unless all are contraindicated.
a. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®) or interferon-beta 1b (Betaseron®)
b. Dimethyl fumarate (Tecfidera®)
c. Glatiramer acetate (Copaxone®)
d. Natalizumab (Tysabri®)
e. Teriflunomide (Aubagio®)
f. Fingolimod (Gilenya®)
g. Diroximel fumarate (Vumerity®)
h. Ozanimod hydrochloride (Zeposia®)
i. Siponimod (Mayzent®)

*Adequate trial is defined as at least 6 months of continuous therapy. Discontinuation of therapy due to drug intolerance will not be considered as failure to therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
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.

OTHER CRITERIA

N/A

LIDOCAINE PATCH

MEDICATION(S)
LIDOCAINE 5% PATCH, LIDODERM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Must have a diagnosis of post-herpetic neuralgia, diabetic peripheral neuropathy, or neuropathic pain

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

LONG ACTING OPIOIDS

MEDICATION(S)

BELBUCA, BUPRENORPHINE, BUTRANS, HYDROCODONE BITARTRATE ER, HYDROMORPHONE ER, HYSINGLA ER, KADIAN, MORPHABOND ER, MORPHINE SULFATE ER 10 MG CAP, MORPHINE SULFATE ER 100 MG CAP, MORPHINE SULFATE ER 120 MG CAP, MORPHINE SULFATE ER 20 MG CAP, MORPHINE SULFATE ER 30 MG CAP, MORPHINE SULFATE ER 40 MG CAP, MORPHINE SULFATE ER 45 MG CAP, MORPHINE SULFATE ER 50 MG CAP, MORPHINE SULFATE ER 60 MG CAP, MORPHINE SULFATE ER 75 MG CAP, MORPHINE SULFATE ER 80 MG CAP, MORPHINE SULFATE ER 90 MG CAP, OXYCODONE HCL ER, OXYCONTIN, OXYMORPHONE HCL ER, XTAMPZA ER, ZOHYDRO ER

COVERED USES

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit. Coverage for Medicaid is limited to conditions listed on the Prioritized List of Health Care Services.

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. Request is for a funded condition (new starts to long acting opioids will not be allowed for unfunded condition) Note: Management of pain associated with back or spine conditions with long-acting opioids is not funded by the OHP. Other conditions, such as fibromyalgia, TMJ, neuropathy, tension headache and pelvic pain syndrome are also not funded by the OHP.

2. 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 other chronic pain:

i. Documentation of chronic 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) AND
v. Documentation of a signed pain management agreement between the prescriber and patient
3. The following drug-specific criteria must be met in addition to the above criteria:
a. For Belbuca®: Documentation of trial and failure of Butrans® (buprenorphine transdermal)
b. 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 other 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. For requests for un-funded conditions
a. Documentation of a plan to discontinue long acting opioids or documentation that discontinuation of the long acting opioid is not clinically appropriate or unsafe

QUANTITY LIMIT:
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.
Note: To avoid abrupt discontinuation, a 90-day approval may be authorized for patients established on long acting opioids to allow for submission of documentation of appropriate monitoring, medical necessity, and/or plan for discontinuation for un-funded conditions

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, 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 (6) 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. Documentation of trial and failure, contraindication, or intolerance to two (2) of the following drug classes:

a. Anti-spasmodic agent [e.g. dicyclomine (Bentyl®)]
b. Tricyclic antidepressants [e.g. amitriptyline (Elavil®)]
c. Opioid mu receptor agonists [e.g., loperamide (Imodium?), diphenoxylate (Lomotil?)]

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.

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 approved for three (3) months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA

N/A

LUXTURNA - MEDICAL BENEFIT

MEDICATION(S)
LUXTURNA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following must be met:
1. Confirmed biallelic RPE65 gene mutation, and
2. Has not previously had the intended treatment eye treated with gene therapy for retinal dystrophy RPE65 mutations, and
3. Documentation by an ophthalmologist within the previous six (6) months of BOTH of the following:
a. Presence of sufficient viable retinal cells in the intended treatment eye as evidenced by an area of retina within the posterior pole of more than 100 micrometer thickness shown on optical coherence tomography, and
b. The member has remaining light perception in the intended treatment eye

AGE RESTRICTION
Approved for 12 months of age and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an ophthalmologist from a certified Luxturna® administration site

COVERAGE DURATION
Authorization is limited to one treatment course per eye per lifetime.

OTHER CRITERIA
N/A

MAVENCLAD

MEDICATION(S)
MAVENCLAD

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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, DOJOLVI, MIGLUSTAT, RAVICTI, SODIUM PHENYLBUTYRATE, ZAVESCA

COVERED USES

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

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)

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

N/A

MEPRON

MEDICATION(S)
ATOVAQUONE, MEPRON

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For prevention or treatment of pneumocystis pneumonia (PCP): Documented trial and failure, intolerance or contraindication to trimethoprim/sulfamethoxazole

For Babesiosis, all of the following criteria must be met:
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).

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: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes
For Babesiosis: Initial and reauthorization approved for 10 day treatment course.

OTHER CRITERIA
N/A

MIACALCIN

MEDICATION(S)
MIACALCIN

COVERED USES
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit.

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

MILLIPRED

MEDICATION(S)
MILLIPRED, MILLIPRED DP, PREDNISOLONE 10 MG/5 ML SOLN

COVERED USES
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit and alcoholic hepatitis

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 will be approved for 3 months. Reauthorization will be approved for 6 months.

OTHER CRITERIA
Documented trial, failure, intolerance or contraindication to generic prednisolone phosphate solution and prednisone (tablets or solution).
OR
Use is for alcoholic hepatitis and Maddrey Discriminant Function (MDF) score is greater than or equal to 32

MIRCERA - MEDICAL BENEFIT

MEDICATION(S)
MIRCERA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For the treatment of adults with anemia associated with chronic kidney disease:
1. Documented Hemoglobin (HGB) levels of less than or equal to 10g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior to initiation of therapy
2. 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%

For the treatment of pediatric patients 5 to 17 years of age who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA:
1. Documented hemodialysis for at least 8 weeks
2. Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least 8 weeks prior to initiation of therapy
3. Documented stable hemoglobin (HGB) levels for at least 8 weeks prior to initiation of therapy.

Reauthorization:
1. Documentation of continued medical necessity (e.g., ongoing chronic kidney disease)
2. Documented HGB levels of less than or equal to 12g/dl or HCT levels of less than or equal to 36% within previous 30 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA

MYALEPT

MEDICATION(S)
MYALEPT

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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 ?U/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
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit.

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)

NEW FORMULATION WITHOUT ESTABLISHED BENEFIT

MEDICATION(S)

ABSORICA, ABSORICA LD, ACANYA, ACTICLATE, ADAPALENE 0.1% LOTION, ADHANSIA XR, ADZENYS ER, ADZENYS XR-ODT, AMPHETAMINE, AMRIX, AZELASTINE-FLUTICASONE, BIDIL, BRYHALI, CALCIPOTRIENE 0.005% FOAM, CARBINOXAMINE MALEATE 6 MG TAB, CARDURA XL, CHLORZOXAZONE 375 MG TABLET, CHLORZOXAZONE 750 MG TABLET, CLARINEX-D 12 HOUR, CLINDAGEL, CLIND PH-BENZOYL PERO 1.2-2.5%, CLINDAMYCIN PHOS-TRETINOIN, CLINDAMYCIN PHOSPHATE 1% GEL, COMBIGAN, CONJUPRI, CONSENSI, CONZIP, CUPRIMINE, CYCLOBENZAPRINE HCL ER, DERMASORB HC, DERMASORB TA, DESLORATADINE 2.5 MG ODT, DESLORATADINE 5 MG ODT, DESONATE, DESONIDE 0.05% GEL, DESOXIMETASONE 0.25% SPRAY, DICLOFENAC, DIFFERIN 0.1% LOTION, DORYX, DORYX MPC, DOXYCYCLINE 50 MG TABLET, DOXYCYCLINE HYC DR 100 MG TAB, DOXYCYCLINE HYC DR 150 MG TAB, DOXYCYCLINE HYC DR 200 MG TAB, DOXYCYCLINE HYC DR 50 MG TAB, DOXYCYCLINE HYC DR 75 MG TAB, DOXYCYCLINE HYC DR 80 MG TAB, DOXYCYCLINE HYCLATE 150 MG TAB, DOXYCYCLINE HYCLATE 75 MG TAB, DOXYCYCLINE IR-DR, DOXYCYCLINE MONO 150 MG CAP, DOXYCYCLINE MONO 75 MG CAPSULE, DUEXIS, DUOBRII, DURLAZA, DUTOPROL, DYMISTA, ECOZA, EDLUAR, EVEKEO ODT, EZALLOR SPRINKLE, FENOFIBRATE 150 MG CAPSULE, FENOFIBRATE 50 MG CAPSULE, FORTAMET, FOSAMAX PLUS D, GIMOTI, GLUMETZA, GOCOVRI, GONITRO, GRALISE, HALOBETASOL PROP 0.05% FOAM, HEMADY, HYDROCORT BUTY 0.1% LIPID CRM, HYDROCORT BUTY 0.1% LIPO CREAM, HYDROCORTISONE BUTYR 0.1% LOTN, IMPEKLO, IMPOYZ, INDOMETHACIN 20 MG CAPSULE, KENALOG, KITABIS PAK, LEXETTE, LICART, LIDOVIX, LIPOFEN, LOCOID 0.1% LOTION, LOCOID LIPOCREAM, LORZONE, LYRICA CR, MELOXICAM 10 MG CAPSULE, MELOXICAM 5 MG CAPSULE, METFORMIN ER GASTRIC, METFORMIN ER OSMOTIC, METOCLOPRAMIDE HCL ODT, METOPROLOL SUCCINATE ER-HCTZ, MINOCYCLINE ER, MINOCYCLINE ER 105 MG TABLET, MINOCYCLINE ER 115 MG TABLET, MINOCYCLINE ER 55 MG TABLET, MINOCYCLINE ER 65 MG TABLET, MINOCYCLINE ER 80 MG TABLET, MINOLIRA ER, MIRAPEX ER, MONDOXYNE NL 75 MG CAPSULE, MONODOX 75 MG CAPSULE, NALOCET, NAPRELAN, NAPROXEN SODIUM CR, NAPROXEN SODIUM ER, NEO-SYNALAR 0.5%-0.025% CREAM, NORITATE, OKEBO, OMEPPI, OMEPRAZOLE-SODIUM BICARBONATE, ONEXTON, ONMEL, ONZETRA XSAIL, ORACEA, ORTIKOS, OXYCODONE-ACETAMINOPHN 2.5-300, PENICILLAMINE 250 MG CAPSULE, PENNSAID, PRAMIPEXOLE ER, PRESTALIA, QMIIZ ODT, RAYOS, RELAFEN DS, REQUIP XL 12 MG TABLET, REQUIP XL 6 MG TABLET, REQUIP XL 8 MG TABLET, RETIN-A MICRO, RETIN-A MICRO PUMP, ROPINIROLE HCL ER 12 MG TABLET, ROPINIROLE HCL ER 6 MG TABLET, ROPINIROLE HCL ER 8 MG TABLET, RYVENT, SERNIVO, SEYSARA, SOLIQUA 100-33, SOLODYN, SORILUX, SPRITAM, SUMATRIPTAN SUCC-NAPROXEN SOD, TARGADOX, TELMISARTAN-AMLODIPINE, TIVORBEX, TOBRAMYCIN PAK 300 MG/5 ML, TOLSURA, TOPICORT 0.25% SPRAY, TOSYMRA, TRAMADOL HCL 100 MG TABLET, TRAMADOL HCL ER 100 MG CAPSULE, TRAMADOL HCL ER 150 MG CAPSULE, TRAMADOL HCL ER 200 MG CAPSULE, TRAMADOL HCL ER 300 MG

CAPSULE, TRETIN-X 0.05% COMBO PACK, TRETIN-X 0.075% CREAM, TRETIN-X 0.1% COMBO PACK, TRETINOIN MICROSPHERE, TREXIMET, TRIAMCINOLONE 0.147 MG/G SPRAY, TUXARIN ER, TWYNSTA, ULTRAVATE 0.05% LOTION, VELTIN, VERDESO, VIVLODEX, WHYTEDERM TDPAK, WHYTEDERM TRILASIL PAK, XIMINO, XOLEGEL, XULTOPHY 100-3.6, ZEGERID, ZEGERID OTC, ZEMBRACE SYMTOUCH, ZIANA, ZIPSOR, ZOLPIMIST, ZORVOLEX, ZTLIDO, ZUPLENZ

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Requests are generally not approved because the requested drug is effective and available in the standard formulation. In unique circumstances, when the patient has exhausted all available formulary options for the patient's condition, not limited to the requested drug in standard formulation, coverage may be considered on a case-by-case basis given the medical rationale and the clinical evidence provided.

QUANTITY LIMIT:

- Edluar® 5mg and 10mg will be limited to 30 tablets per 30 days
- Gimoti 15 mg Nasal Spray will be limited to 1 bottle per 28 days (9.8 mL per bottle)
- Gocovri 68.5mg limited to 30 capsules per 30 days, 137mg limited to 60 capsules per 30 days
- Lyrica CR 82.5mg, 165mg, 330mg limited to 30 tablets per 30 days
- Treximet is limited to 9 tablets per 30 days
- Zolpimist® will be limited to 1 container (60 doses of 5mg zolpidem) per 30 days

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Gimoti Nasal Spray: Authorization will be approved for three (3) months for each episode of diabetic gastroparesis.
*Treatment with metoclopramide (all dosage forms and route of administration) longer than three (3) months should be avoided due to risk of developing tardive dyskinesia.

For all other drugs, authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA

N/A

NEXLETOL/NEXLIZET

MEDICATION(S)
NEXLETOL, NEXLIZET

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Initial Authorization:
1. Confirmed diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or Familial Hypercholesterolemia
2. Fasting LDL-C equal to or greater than 70 mg/dL despite treatment with therapies below
3. One of the following:
a. Current use of high-intensity statin therapy for at least 3 months, defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily
b. Documented statin intolerance to low dose atorvastatin or rosuvastatin (atorvastatin 10 mg daily or rosuvastatin 5 mg daily) and any other statin at any dose. Statin intolerance is defined as intolerable muscle side effects or biomarker changes (such as elevations in creatinine kinase) that decrease or resolve after discontinuation of therapy with a statin.
4. Current use of ezetimibe 10 mg daily for at least 3 months, or documented intolerance/contraindication to its use.
5. Documentation of current use of a formulary PCSK-9 inhibitor (e.g., Repatha®) or intolerance/contraindication to its use.

For reauthorization: documented response to therapy, as defined by a reduction in fasting LDL-C

AGE RESTRICTION
Approved for adults 18 years of age and older

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

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

OTHER CRITERIA

N/A

NORTHERA

MEDICATION(S)
DROXIDOPA, NORTHERA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization all of the following criteria must be met:
1. Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH)
2. Documentation that neurogenic orthostatic hypotension is caused by one of the following:
a. Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, or pure autonomic failure)
b. Dopamine beta-hydroxylase deficiency
c. Non-diabetic autonomic neuropathy
3. Documentation of a screen for treatable causes of orthostatic hypotension and currently being treated for the identified treatable cause of orthostatic hypotension (See Appendix 1)
4. Documentation of an adequate trial of non-pharmacotherapy measure has been ineffective (See Appendix 2)
5. Documented trial, failure, intolerance or contraindication to both midodrine and fludrocortisone

Reauthorization will require:
1. Documented response to initial therapy (improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out)
2. Documentation that periodic evaluations are being done to assess continued efficacy and medical rationale for continuing therapy, as none of the clinical trials demonstrated continued efficacy beyond 2 weeks of treatment.

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA

N/A

NOURIANZ

MEDICATION(S)
NOURIANZ

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

NPLATE - MEDICAL BENEFIT

MEDICATION(S)
NPLATE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Must meet all of the following:
1. A diagnosis of immune thrombocytopenia (ITP), AND
2. Patient is at risk for bleeding with a platelet count of less than or equal to 30 x 10^9 per liter, AND
3. Treatment by at least one of the following was ineffective or not tolerated:
a. Systemic corticosteroids, OR
b. Immune globulin, OR
c. Splenectomy

Reauthorization will require submission of platelet values demonstrating a response to therapy and a weekly dose below 10 mcg/kg.

QUANTITY LIMITS:
Nplate is available as 125-, 250-, and 500- mcg single-dose vials of lyophilized powder. Quantity approved may be rounded down to nearest available vial size within 10% of calculated dose.

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 up to three (3) months. Reauthorization will be approved for up to six (6) months.

OTHER CRITERIA
N/A

NUCYNTA

MEDICATION(S)
NUCYNTA

COVERED USES
Relief of moderate to severe pain

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
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit

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
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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
Use for non-alcoholic steatohepatitis (NASH)

REQUIRED MEDICAL INFORMATION
For the diagnosis of primary biliary cholangitis:
1. Confirmed diagnosis of primary biliary cholangitis as evidenced 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 six (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

QUANTITY LIMIT:
5 mg tablet: 1 tablet per day

10 mg tablet: 1 tablet per day

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 four (4) months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

OCTREOTIDE INJECTABLES

MEDICATION(S)

BYNFEZIA, OCTREOTIDE ACETATE, SANDOSTATIN, SANDOSTATIN LAR DEPOT

COVERED USES

All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit. The following compendia supported indications may be approved subject to criteria: Acquired immunodeficiency syndrome (AIDS)-related diarrhea, variceal bleeding, chemotherapy-induced diarrhea, oncologic conditions.

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

OPHTHALMIC VEGF INHIBITORS: EYLEA, LUCENTIS, MACUGEN

MEDICATION(S)
BEOVU, EYLEA, LUCENTIS, MACUGEN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Must have one (1) of the following diagnoses and meet any required criteria:
1. Neovascular (wet) age-related macular degeneration (AMD)
a. For ranibizumab (Lucentis®), aflibercept (Eylea®), brolucizumab (Beovu®)
i. Documentation that bevacizumab (Avastin®) has been ineffective, not tolerated, or contraindicated (examples of contradictions include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome)
OR
ii. Rationale is provided why therapy with bevacizumab (Avastin®) is not appropriate for the patient

a. For pegaptanib (Macugen®):
i. Documentation that bevacizumab (Avastin®) and either ranibizumab (Lucentis®) or aflibercept (Eylea®) has been ineffective, not tolerated, or contraindicated
OR
ii. Rationale is provided why therapy is not appropriate for the patient

2. Diabetic macular edema or Diabetic retinopathy
a. For ranibizumab (Lucentis®) or aflibercept (Eylea®):
i. Documentation that bevacizumab (Avastin®) has been ineffective, not tolerated, or contraindicated (examples of contradictions include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome)
OR
ii. Request is for aflibercept (Eylea®) and patients baseline visual acuity is 20/50 or worse
OR
iii. Rationale is provided why therapy with bevacizumab (Avastin®) is not appropriate for member

3. Macular edema following retinal vein occlusion
a. For ranibizumab (Lucentis®) or aflibercept (Eylea®):

i. Documentation that bevacizumab (Avastin®) has been ineffective, not tolerated, or contraindicated (examples of contradictions include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome)
OR
ii. Rationale is provided why therapy with bevacizumab (Avastin®) is not appropriate for the patient

4. Myopic Choroidal Neovascularization (mCNV)
a. Request is for ranibizumab (Lucentis®)

Reauthorization or continuation of therapy:
Documentation of positive response to therapy (such as stabilization or improvement in vision)

QUANTITY LIMITS: Approval may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines and are subject to medical claims audits.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed and administered by an ophthalmologist or retinal specialist

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

OTHER CRITERIA
N/A

ORAL ANTI-CANCER MEDICATIONS

MEDICATION(S)

ABIRATERONE ACETATE, AFINITOR, AFINITOR DISPERZ, ALECENSA, ALKERAN 2 MG TABLET, ALUNBRIG, AYVAKIT, BALVERSA, BEXAROTENE, BOSULIF, BRAFTOVI 75 MG CAPSULE, 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, GAVRETO, GILOTRIF, GLEEVEC, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA, INLYTA, INQOVI, INREBIC, IRESSA, JAKAFI, KISQALI, KISQALI FEMARA CO-PACK, LAPATINIB, LENVIMA, LONSURF, LORBRENA, LYNPARZA, MEKINIST, MEKTOVI, MELPHALAN, NERLYNX, NEXAVAR, NINLARO, NUBEQA, ODOMZO, ONUREG, ORGOVYX, PEMAZYRE, PIQRAY, POMALYST, QINLOCK, RETEVMO, REVLIMID, ROZLYTREK, RUBRACA, RYDAPT, SPRYCEL, STIVARGA, SUTENT, TABRECTA, 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, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VOTRIENT, XALKORI, XOSPATA, XPOVIO, XTANDI 40 MG CAPSULE, YONSA, ZEJULA, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA, ZYTIGA

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

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®)

For patients established on therapy: 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

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

OTHER CRITERIA

N/A

ORAL OCTREOTIDE

MEDICATION(S)
MYCAPSSA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Confirmed diagnosis of acromegaly, AND
2. Documentation of an inadequate response to surgery or pituitary irradiation or patient is not a candidate for surgical resection and pituitary irradiation, AND
3. Patient has been maintained (for at least 6 months) on octreotide injection or lanreotide therapy and responded to and tolerated therapy.

Reauthorization: required 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)

QUANTITY LIMIT:
Octreotide acetate (Mycapssa®) 20 mg DR capsules: 4 capsules per day

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

ORAL RINSES

MEDICATION(S)

AQUORAL, BOCASAL, CAPHOSOL, EPISIL, GELCLAIR, GELX, MUGARD, NEUTRASAL, XEROSTOMIA RELIEF

COVERED USES

Mucositis/stomatitis secondary to chemotherapy or radiation
Xerostomia secondary to chemotherapy or radiation
Sjögren's syndrome

EXCLUSION CRITERIA

Other indications not outlined above

REQUIRED MEDICAL INFORMATION

For mucositis/stomatitis secondary to chemotherapy or radiation
1. Diagnosis of mucositis/stomatitis secondary to chemotherapy or radiation
AND
2. Documented trial, failure, intolerance or contraindication to TWO of the following:
a. Over-the-counter oral anesthetics (e.g. benzocaine products such as OraGel®, Anbesol®)
b. Prescription oral anesthetics (e.g. viscous lidocaine 2%)
c. Saliva substitutes (e.g. Biotene®, Mouth Kote®)
d. Magic mouthwash - a compounded product often containing viscous lidocaine, Maalox®, and diphenhydramine. Multiple formulations are compounded and these may contain different ingredients.
Note: premeasured kits for these solutions are not available on formulary
Reauthorization requires:
1. Documentation of continued need for therapy (e.g., continued chemotherapy and/or radiation)
2. Documentation of initial response to therapy (e.g., reduced signs and symptoms of mucositis, increased ability to tolerate food and beverages)

For xerostomia secondary to chemotherapy or radiation and Sjögren's syndrome
1. Diagnosis of xerostomia secondary to chemotherapy or radiation OR Sjögren's syndrome
AND
2. Documented trial, failure, intolerance or contraindication to both of the following:
a. TWO over the counter saliva substitutes (e.g. Biotene®, Mouth Kote®)
b. Saliva stimulants (e.g., sugar free lozenges or chewing gum)

Reauthorization requires:
1. Documentation of continued need for therapy (e.g., continued chemotherapy and/or radiation)

2. Documentation of initial response to therapy (e.g., reduced signs and symptoms of xerostomia, increased ability to tolerate food and beverages)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

1. For mucositis/stomatitis and xerostomia secondary to chemotherapy or radiation initial authorization and reauthorization will be approved for 6 months.
2. For Sjögren’s syndrome initial authorization and reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA

N/A

OSMOLEX ER

MEDICATION(S)
OSMOLEX ER

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

OXAYDO/ROXYBOND

MEDICATION(S)
OXAYDO, ROXYBOND

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
Treatment of opioid dependence

REQUIRED MEDICAL INFORMATION
1. Documentation of high risk for opioid abuse:
a. Based on provider clinical judgment or screening assessment (including having a history of opioid abuse) OR
b. Family or household member with a history of opioid abuse

QUANTITY LIMIT:
Oxaydo: Limited to 300 tablets per 30 days
Roxybond 15 mg: Limited to 150 tablets per 30 days
Roxybond 30 mg: Limited to 60 tablets per 30 days
Opioid doses greater than 120 mg MED per day in the treatment of chronic non-malignant pain requires prior authorization
See Policy Maximum Allowable Opioid Dose in Non-Malignant Chronic Pain ORPTCANA031

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for up to 6 months. Reauthorization will be approved based on documentation that the patient is abstaining from use of other opiates (verified by claims history). Reauthorizations will be approved for 1 year.

OTHER CRITERIA
N/A

OXBRYTA

MEDICATION(S)
OXBRYTA

COVERED USES
N/A

EXCLUSION CRITERIA
Used in combination with crizanlizumab (Adakveo®)

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Confirmed medical history or diagnosis of sickle cell disease
2. Documented hemoglobin of less 10.5 g/dL taken within one month prior to initiating therapy
3. Documentation that patient meets one of the following:
a. Patient will continue taking hydroxyurea with the requested therapy and patient has been on a maximally tolerated dose of hydroxyurea for at least six (6) months
b. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least six (6) months
c. Patient has had an intolerance or contraindication to hydroxyurea (For many patients myelosuppression is dose-dependent and reversible, intolerance due to myelosuppression will only be considered if patient continues to experience myelosuppression despite dose adjustments)

Reauthorization:
For initial reauthorization documentation of an increase in hemoglobin from baseline of at least 1 g/dL and for subsequent reauthorization documentation that an increase of at least 1 g/dL from baseline has been maintained

QUANTITY LIMIT:
Three (3) tablets per day

AGE RESTRICTION
May be approved for patients 12 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a hematologist or a provider experienced with the treatment of Sickle Cell Disease

COVERAGE DURATION

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

OTHER CRITERIA

N/A

OXERVATE

MEDICATION(S)
OXERVATE

COVERED USES
N/A

EXCLUSION CRITERIA
Retreatment of the same eye

REQUIRED MEDICAL INFORMATION
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 (2) 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 (one (1) vial) per day (If both eyes are being treated a quantity of 2 mL (two (2) vials) a day will be allowed

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be approved for eight (8) weeks, an additional eight (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
N/A

OXLUMO

MEDICATION(S)
OXLUMO

COVERED USES
N/A

EXCLUSION CRITERIA
1. Patients with a history of liver transplant
2. Patients with an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m2

REQUIRED MEDICAL INFORMATION
Initial authorization for new starts:
1. Patient has a diagnosis of primary hyperoxaluria type 1 (PH1)
2. Diagnosis of PH1 has been confirmed by one of the following:
a. Genetic testing demonstrating mutation in the alanine: glyoxylate aminotransferase (AGXT) gene
b. Liver biopsy demonstrating significantly decreased or absent alanine: glyoxylate aminotransferase (AGT) enzyme activity
3. Documentation of one of the following:
a. Elevated urine oxalate (UOx) excretion as measured by body surface area-normalized daily UOx output greater than upper limit of normal (ULN)
b. Elevated UOx excretion as measured by UOx: creatinine ratio above age-specific upper limit of normal (ULN) OR
c. Elevated plasma oxalate (POx) concentration (POx concentration greater than ULN)
4. Documentation of a trial of high fluid intake of at least 3 liters per meter-squared of Body Surface Area (BSA) per day and that high fluid intake will continue with therapy
5. Concurrent use of pyridoxine or previous trial of at least 3 months with no significant improvement in urine oxalate concentration

Reauthorization or continuation of therapy:
1. Documentation of a clinically significant reduction in urine or plasma oxalate levels relative to pre-treatment baseline
2. Patient continues with concurrent high fluid intake (at least 3 liters per meter-squared BSA per day) and pyridoxine (unless individual is a pyridoxine non-responder)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

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

OTHER CRITERIA

N/A

OXYMORPHONE

MEDICATION(S)
OPANA, OXYMORPHONE HCL

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

Coverage for Medicaid 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.

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

PALFORZIA

MEDICATION(S)
PALFORZIA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
• Uncontrolled asthma
• History of eosinophilic esophagitis and other eosinophilic gastrointestinal disease
• Severe or life-threatening anaphylaxis in the last 60 days

REQUIRED MEDICAL INFORMATION
Initial Authorization requires all of the following criteria to be met:
1. Documented history of an anaphylactic allergic reaction to peanuts or peanut-containing foods that required epinephrine injection that occurred between 60 days and one year prior to treatment
2. Confirmed peanut allergy by at least one (1) of the following:
a. Positive skin prick test (SPT) response to peanut with a wheal diameter of 3mm or greater when compared to the negative control
b. Serum immunoglobulin E (IgE) to peanut of 0.35 kUA/L or greater (kUA/L = kilos of allergen specific units per liter)
3. Documentation that patient will continue to maintain a peanut-avoidant diet
4. Documentation that patient has an active prescription for auto-injectable epinephrine
5. Provider attestation that the patient is a good candidate for therapy (e.g., will be able to maintain daily dosing requirements after initiation and dose titration)

For reauthorization, all of the following criteria must be met:
1. Documentation that patient is tolerating peanut allergen immunotherapy at doses greater than 3 mg and is not exceeding 300 mg daily
2. Documentation that the patient is not experiencing adverse events on Palforzia® (e.g., recurrent asthma exacerbations, persistent loss of asthma control, persistent heartburn, dysphagia, persistent abdominal pain)
3. Provider attestation that the patient continues to be to comply with daily dosing requirements
4. Documentation that patient has an active prescription for auto-injectable epinephrine

AGE RESTRICTION
For Initiation of therapy: Aged 4 to 17 years
For Continuation (up-dosing or maintenance): Aged 4 years or older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, an allergist and/or immunologist.

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA

N/A

PALYNZIQ

MEDICATION(S)
PALYNZIQ

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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, REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

COVERED USES

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For all indications must have documentation of:
a. One of the following:
1) Current use of high-intensity statin therapy for at least 3 months, defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily, OR
2) Documented statin intolerance to low dose atorvastatin or rosuvastatin (atorvastatin 10 mg daily or rosuvastatin 5 mg daily) and any other statin 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.
AND
2. Current use of ezetimibe 10 mg daily for at least 3 months, or documented intolerance/contraindication to its use. If patient is more than 30% above the goal low-density lipoprotein (LDL) level outlined in the hyperlipidemia criteria below, this criterion for ezetimibe may be waived.
AND
3. Must meet listed criteria below for each specific diagnosis:
a. For familial hypercholesterolemia (FH), both of the following:
i. Confirmed diagnosis by one of the following:
1. 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
2. Low density lipoprotein cholesterol (LDL-C) greater than 330 mg/dL OR
3. LDL-C greater than 190 mg/dL and two of the following:
a. Presence of tendon xanthomas in patient or in first- or second-degree relatives
b. Personal history of premature atherosclerotic cardiovascular disease (ASCVD) in men less than 55 years or women less than 60 years
c. First-degree relative with premature ASCVD (men less than 55 years, women less than 60 years)
ii. Documentation of current (within previous 3 months) LDL-C greater than 100 mg/dL, taken after at least 3 months of continuous therapy with statin and ezetimibe outlined in criterion 1 above
b. For ASCVD, both of the following:

i. Documentation of current (within previous 3 months) LDL-C greater than 70 mg/dL, taken after at least 3 months of continuous therapy with statin and ezetimibe outlined in criterion 1 above
ii. Documentation of very high-risk clinical ASCVD, defined as history of multiple ASCVD events [i.e., acute coronary syndrome (ACS) within previous 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease] OR one ASCVD event and multiple of the following high-risk conditions:
1. Age 65 years and older
2. Heterozygous familial hypercholesterolemia
3. History of coronary revascularization (CABG or PCI)
4. Diabetes mellitus
5. Hypertension
6. Chronic kidney disease
7. Current smoking
8. Persistently elevated LDL-C above 100 despite maximally tolerated statin therapy and ezetimibe
9. History of congestive heart failure

Initial Reauthorization: Documentation of response to therapy, defined as a decrease in LDL-C levels of at least 40% from pre-treatment levels.

QUANTITY LIMIT:
Two injections (2.0 mL) per 28 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For ASCVD: 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 six months.
Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A

PEDIATRIC ANALGESICS

MEDICATION(S)

ACETAMINOPHEN-CODEINE, ASA-BUTALB-CAFFEINE-CODEINE, ASCOMP WITH CODEINE, BUTALB-ACETAMINOPH-CAFF-CODEIN, BUTALBITAL COMPOUND-CODEINE, CAPCOF, CARISOPRODOL-ASPIRIN-CODEINE, CHERATUSSIN AC, CODEINE PHOSPHATE, CODEINE SULFATE, CODEINE-GUAIFENESIN, CODITUSSIN AC, FIORICET WITH CODEINE, FIORINAL WITH CODEINE #3, G TUSSIN AC, GUAIATUSSIN AC, GUAIFENESIN AC, GUAIFENESIN DAC, GUAIFENESIN-CODEINE, LORTUSS EX, M-CLEAR WC, M-END PE, MAR-COF BP, MAR-COF CG, MAXI-TUSS AC, NINJACOF-XG, POLY-TUSSIN AC, PRO-RED AC, PROMETHAZINE VC-CODEINE, PROMETHAZINE-CODEINE, PROMETHAZINE-PHENYLEPH-CODEINE, QDOLO, RYDEX, 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, TUZISTRA XR, TYLENOL-CODEINE NO.3, TYLENOL-CODEINE NO.4, ULTRACET, ULTRAM, VIRTUSSIN AC, VIRTUSSIN DAC, Z-TUSS AC, ZODRYL AC 25, ZODRYL AC 30, ZODRYL AC 35, ZODRYL AC 40, ZODRYL AC 50, ZODRYL AC 60, ZODRYL AC 80, ZODRYL DAC 25, ZODRYL DAC 30, ZODRYL DAC 35, ZODRYL DAC 40, ZODRYL DAC 50, ZODRYL DAC 60, ZODRYL DAC 80, ZODRYL DEC 25, ZODRYL DEC 30, ZODRYL DEC 35, ZODRYL DEC 40, ZODRYL DEC 50, ZODRYL DEC 60, ZODRYL DEC 80

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 one (1) tablet per one (1) day
Ultram® 50 mg, tramadol 50mg: limit of eight (8) tablets per one (1) day
Qdolo® 5 mg/ml solution: limit 80 ml per 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 one (1) month

OTHER CRITERIA
N/A

POTASSIUM LOWERING AGENTS

MEDICATION(S)
LOKELMA, VELTASSA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All the following criteria are required:
1. Documentation of confirmed diagnosis of hyperkalemia (greater than or equal to 5.1 mEq/L)
AND
2. Documented trial and failure, or contraindication to sodium polystyrene sulfonate oral suspension (Kayexalate®, Kionex®)
AND
3. If patient is receiving concurrent angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) therapy: documentation of an attempt to optimize the dose of all current renin-angiotensin –aldosterone (RAAS) inhibitors (e.g. ACE-I, ARB, aldosterone antagonists) to minimize hyperkalemia

Reauthorization will require all of the following criteria:
1. Documentation that patient achieved normal potassium levels (3.5-5.0 mEq/L) within the last three months
AND
2. Patient is continuing on RAAS inhibitor therapy or medical rationale is provided for continuing therapy (e.g., patient remains at high risk for recurrence of hyperkalemia)

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization: 6 months
Reauthorization: 12 months

OTHER CRITERIA

N/A

PREVYMIS

MEDICATION(S)
PREVYMIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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)

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
N/A

PROCYSBI

MEDICATION(S)
PROCYSBI

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization:
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 immediate release cysteamine capsules (Cystagon®).

AGE RESTRICTION
1 year of age and older

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

PROMACTA

MEDICATION(S)
PROMACTA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization of chronic immune thrombocytopenia (ITP):
1. Patient is at risk for bleeding with a platelet count of less than 30,000 cells per microliter
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

For initial authorization of severe aplastic anemia:
1. Patient is at risk for bleeding with a platelet count of less than 30,000 cells per microliter

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 50,000 cells per microliter

AGE RESTRICTION
N/A

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

COVERAGE DURATION
For ITP or severe aplastic anemia: Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A

PROPHYLACTIC HEREDITARY ANGIOEDEMA THERAPY

MEDICATION(S)

CINRYZE, HAEGARDA, ORLADEYO, TAKHZYRO

COVERED USES

N/A

EXCLUSION CRITERIA

Combination prophylaxis therapy with Cinryze®, Haegarda®, Takhzyro®, or Orladeyo®

REQUIRED MEDICAL INFORMATION

All of the following must be met:

1. Documentation of 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. Documentation of greater than or equal to 2 HAE attacks per month on average for the past 3 months despite removal of triggers (e.g., estrogen containing oral contraceptive, angiotensin converting enzyme inhibitors) unless medically necessary

AND

3. 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) ANGPT1, PLG, KNG1 gene 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
Orladeyo®: 30 capsules (150mg each) per 30-day supply

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

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
N/A

PROTON PUMP INHIBITORS

MEDICATION(S)
ACIPHEX SPRINKLE, DEXILANT, ESOMEPRAZOLE DR 10 MG PACKET, ESOMEPRAZOLE DR 20 MG PACKET, ESOMEPRAZOLE DR 40 MG PACKET, ESOMEPRAZOLE STRONTIUM, NEXIUM DR 10 MG PACKET, NEXIUM DR 2.5 MG PACKET, NEXIUM DR 20 MG PACKET, NEXIUM DR 40 MG PACKET, NEXIUM DR 5 MG PACKET, RABEPRAZOLE DR 10 MG SPRNKL CP

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

PROVENGE - MEDICAL BENEFIT

MEDICATION(S)
PROVENGE

COVERED USES
N/A

EXCLUSION CRITERIA
• Concomitant use of chemotherapy, systemic steroid medications at greater than physiologic replacement doses and/or other systemic immunosuppressive agents to treat autoimmune disease or prevent allogeneic transplant rejection
• Presence of hepatic or other visceral metastases

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met:
1. Asymptomatic or minimally symptomatic metastatic disease (e.g. no opioid use for malignant cancer pain)
2. Castrate-resistant or castration-recurrent prostate cancer, defined as both of the following:
a. Radiographic, clinical or biochemical [i.e., prostate-specific antigen (PSA)] progression despite therapy with androgen ablation therapy (e.g. orchiectomy, GnRH agonists/antagonists)
AND
b. Testosterone level less than 50 ng/dL
3. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
4. Life expectancy more than six (6) months

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Authorization will be approved for 3 complete doses administered at approximately 2 week intervals (6 weeks) for one course of therapy per lifetime.

OTHER CRITERIA
N/A

PULMONARY ARTERIAL HYPERTENSION

MEDICATION(S)

ADCIRCA, ADEMPAS, ALYQ, AMBRISENTAN, BOSENTAN, EPOPROSTENOL SODIUM, FLOLAN, LETAIRIS, OPSUMIT, ORENITRAM ER, REMODULIN, REVATIO 10 MG/12.5 ML VIAL, REVATIO 10 MG/ML ORAL SUSP, SILDENAFIL 10 MG/12.5 ML VIAL, SILDENAFIL 10 MG/ML ORAL SUSP, TADALAFIL 20 MG TABLET, TRACLEER, TREPROSTINIL, TYVASO, TYVASO INSTITUTIONAL START KIT, TYVASO REFILL KIT, TYVASO STARTER KIT, UPTRAVI, VELETRI, VENTAVIS

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 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 parenteral injection (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
• Tadalafil (Adcirca®): 2 tablets/day

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
N/A

QUDEXY XR, TROKENDI XR

MEDICATION(S)
QUDEXY XR, TOPIRAMATE ER, TROKENDI XR

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmed diagnosis of one of the following conditions:
a. Seizure disorder
b. Migraine Headaches

Reauthorization for migraine headaches requires documented positive response to therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Migraine Headaches: Initial authorization will be approved for 3 months. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

For seizure disorders: Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A

RADICAVA - MEDICAL BENEFIT

MEDICATION(S)
RADICAVA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial criteria:
1. Documentation of ALL of the following:
a. Diagnosis of definite or probable amyotrophic lateral sclerosis (ALS) per the El Escorial (Airlie House) Criteria
b. Diagnosis of ALS within the last 2 years
c. Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) with greater than or equal to 2 points in each individual item (Use Appendix 1)
d. Forced vital capacity (FVC) greater than or equal to 80% (taken within the past 3 months)

2. Dosing is in accordance with the FDA approved labeling

Reauthorization criteria:
1. Documentation of a clinical benefit from therapy such as slowing of disease progression or stabilization of functional ability and maintenance of ADLs
2. Patient is not dependent on invasive ventilation or tracheostomy
3. Dosing is in accordance with the FDA approved labeling

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist with expertise in ALS.

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

OTHER CRITERIA
N/A

REBLOZYL

MEDICATION(S)
REBLOZYL

COVERED USES
N/A

EXCLUSION CRITERIA
1. Evidence of active pregnancy
2. History of thrombosis

REQUIRED MEDICAL INFORMATION
For initial authorization for beta-thalassemia, all of the following must be met:
1. Diagnosis of beta-thalassemia, which can be confirmed by one of the following:
a. Hemoglobin analysis or genetic testing
b. Complete blood count that showed reduced Hgb level (less than seven (7) g/dL), mean corpuscular volume (MCV) between 50 and 70 fL, and mean corpuscular hemoglobin (MCH) between 12 and 20 pg
c. Peripheral blood smear results that show red blood cell (RBC) morphologic changes including microcytosis, hypochromia, anisocytosis, poikilocytosis and nucleated RBC
2. Documentation that patient is transfusion-dependent, defined as receiving at least 6-20 units RBC transfusions every 24 weeks
3. Documented baseline Hgb level of at least 9 g/dL, drawn within the previous 30 days

For continuation of therapy for beta-thalassemia beyond 9 weeks, ongoing documentation of patient response to therapy must include maintenance of reduced transfusion levels

For initial authorization for myelodysplastic syndrome (MDS), all of the following must be met:
1. Diagnosis of MDS with ring sideroblasts (MDS-RS), or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
2. Score of very low to intermediate risk based on the Revised International Prognostic Scoring System
3. Documentation that patient requires RBC transfusions of at least two (2) units every eight (8) weeks
4. One of the following:
a. Documented trial and failure [of at least two (2) months], intolerance, or contraindication to erythropoiesis-stimulating agents (i.e., erythropoietin or darbepoetin)
b. Documentation of endogenous erythropoietin level greater than 500 mU/mL

For reauthorization for MDS-RS: Documentation that patient was able to achieve transfusion independence for at least eight weeks during previous treatment period

AGE RESTRICTION

At least 18 years of age

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a hematologist

COVERAGE DURATION

Beta-thalassemia: Initial authorization will be for 9 weeks. Reauthorization will be for one (1) year.
MDS-RS: Initial authorization will be for 6 months. Reauthorization will be for one (1) year

OTHER CRITERIA

N/A

REGRANEX

MEDICATION(S)
REGRANEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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, documentation must show an adequate response defined as a 30% reduction or greater in ulcer size. There is no medical evidence to justify ongoing treatment after 180 days of Regranex® treatment.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

RESCUE MEDICATIONS FOR EPILEPSY

MEDICATION(S)
NAYZILAM, VALTOCO

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

REYVOW

MEDICATION(S)
REYVOW

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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
Initial authorization and reauthorization will be approved for 6 months

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

OTHER CRITERIA
Diagnosis of migraine headaches AND one of the following:
• Trial of and inadequate response or intolerance to two (2) oral triptans (e.g., sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan) and one (1) additional triptan formulation (e.g. oral disintegrating tablet, nasal spray, injection) OR
• One of the following cardiovascular or non-coronary vascular contraindications to use of triptans:
o Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal’s angina)
o History of stroke or transient ischemic attack (TIA)
o Peripheral vascular disease
o Ischemic bowel disease
o Uncontrolled hypertension

Reauthorization: Documentation of treatment success as demonstrated reduction of migraine pain or freedom from migraine symptoms.

QUANTITY LIMIT:
Lasmiditan (Reyvow) tablet: 4 tablets per 30 days

RITUXIMAB

MEDICATION(S)
RIABNI, RITUXAN, RITUXAN HYCELA, RUXIENCE, TRUXIMA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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

For Rheumatoid Arthritis:
1. Documentation of trial, failure, intolerance, or contraindication to at least one (1) of the following targeted immune modulators: Enbrel®, Humira®, Remicade®, or Simponi® Aria.
AND
2. Documentation that rituximab will be used concurrently with methotrexate. If intolerance or contraindication to methotrexate, then in combination with another disease-modifying antirheumatic drug (DMARD) (e.g., leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy.

For Vasculitis – including antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [e.g., Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)] and refractory polyarteritis nodosa (resistant to cyclophosphamide):
1. Documentation that rituximab will be given in combination with glucocorticoids
AND
2. Documentation of severe disease (e.g., critical organ system involvement)

For Immune Thrombocytopenia (ITP):
1. Documentation of trial, failure, intolerance, or contraindication to systemic corticosteroid therapy
AND
2. Documentation of active bleeding, or high-risk of bleeding, or a platelet count less than 30,000 cells per microliter

For Relapsing and Remitting Multiple Sclerosis (RRMS):

1. One (1) of the following:
a. Documentation of trial, failure, or intolerance to at least two disease modifying therapies indicated for RRMS
OR
b. Documentation that patient has highly active or aggressive disease

For Refractory Myasthenia Gravis:
1. Documentation that patient has severely impaired function due to myasthenia gravis
AND
2. Documented trial, failure, intolerance or contraindication to at least two (2) 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

For Autoimmune Hemolytic Anemia (AIHA):
1. In patients diagnosed with warm AIHA
a. Documentation of trial, failure, intolerance, or contraindication to glucocorticoids
OR
2. In patients diagnosed with cold AIHA or cold agglutinin disease

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, rheumatologist, neurologist (in the case of RRMS, NMO), dermatologist (in the case of PV), or nephrologist (in the case of renal disease).

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

OTHER CRITERIA
N/A

SABRIL

MEDICATION(S)
SABRIL, VIGABATRIN, VIGADRONE

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

Reauthorization requires documentation of positive clinical response and continued periodic vision assessment.

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
For infantile spasms, initial authorization and reauthorization will be approved for 1 year.
For complex partial seizures, authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A

SCENESSE

MEDICATION(S)
SCENESSE

COVERED USES
N/A

EXCLUSION CRITERIA
1. Current Bowen's disease, basal cell carcinoma, or squamous cell carcinoma
2. Personal history of melanoma or dysplastic nevus syndrome
3. Erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP) with significant hepatic involvement

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. Confirmed diagnosis of erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP) by one of the following:
a. Gene sequencing showing an FECH, CLPX, or ALAS2 mutation
b. Elevated total erythrocyte protoporphyrin greater than 80 mcg/dL
c. Erythrocyte fractionation shows more than 50% metal-free vs. zinc protoporphyrin
2. Documentation of characteristic symptoms of EPP/XLP phototoxicity (e.g., intolerance to light with symptoms including itching, burning, pain, erythema, or scarring of the skin on contact with sunlight)
3. Documentation that sun avoidance and use of sunscreen and protective clothing have proven inadequate in controlling EPP/ XLP -associated painful skin reactions
4. Documentation that the condition is having a significant impact on quality of life (QOL)

For reauthorization:
1. Documentation of a positive response to therapy by of one of the following:
a. Decreased severity and number of phototoxic reactions
b. Increased duration of sun exposure
c. Increased quality of life
2. For request of more than 3 implants per year: medical justification must be provided addressing why member needs coverage for more than 6 months out of the year (afamelanotide is typically given during periods of high sunlight exposure, e.g. from spring to autumn)

AGE RESTRICTION
Approved for 18 years of age or older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with a dermatologist or porphyria specialist

COVERAGE DURATION

Initial and reauthorization will be approved for 6 months for 3 implants (Medical justification is required for requests beyond 3 implants for seasonal coverage)

OTHER CRITERIA

N/A

SECOND AND THIRD GENERATION ANTIHISTAMINES

MEDICATION(S)

24HR ALLERGY RELIEF, ALAVERT, KRO ALL DAY ALLERGY 10 MG SFGL, GNP ALL DAY ALLERGY 10 MG SFGL, ALL DAY ALLERGY-D, ALLEGRA ALLERGY, ALLEGRA-D 12 HOUR, ALLEGRA-D 24 HOUR, ALLER-EASE, ALLER-FEX, ALLER-TEC D, ALLERCLEAR D-12HR, ALLERCLEAR D-24HR, ALLERGY COMPLETE-D, ALLERGY D-12, ALLERGY RELIEF 10 MG ODT, ALLERGY RELIEF 180 MG TABLET, ALLERGY RLF(CETRZN) 10 MG SFGL, CVS ALLERGY RELIEF 180 MG TAB, CVS ALLERGY RELIEF 5 MG TABLET, CVS ALLERGY RELIEF 60 MG TAB, CVS ALLERGY(CETRZN) 10 MG SFGL, EQ ALLERGY RELIEF 180 MG TAB, GNP ALLERGY RELIEF 180 MG TAB, GNP ALLERGY RELIEF 5 MG TABLET, HM ALLERGY RELIEF 180 MG TAB, KRO ALLERGY RELIEF 180 MG TAB, KRO ALLERGY RELIEF 60 MG TAB, PUB ALLERGY RELIEF 180 MG TAB, RA ALLERGY RELIEF 180 MG TAB, SM ALLERGY RELIEF 10 MG ODT, ALLERGY RELIEF D, ALLERGY RELIEF D-12, ALLERGY RELIEF D-24HR, ALLERGY RELIEF-D, ALLERGY RELIEF-D12, ALLERGY RELIEF-NASAL DECONGEST, ALLERGY+CONGESTION RELIEF-D, ALLERGY-CONGESTION 12HR, ALLERGY-CONGESTION ER, ALLERGY-CONGESTION RELIEF, ALLERGY-CONGESTION RELIEF 12HR, ALLERGY-CONGESTION RELIEF-D, CETIRI-D, CETIRIZINE HCL 10 MG CHEW TAB, CETIRIZINE HCL 5 MG CHEW TAB, CETIRIZINE HCL 5 MG/5 ML SOLN, CETIRIZINE-PSEUDOEPHEDRINE ER, CHILDREN'S ALLEGRA ALLERGY, CVS CHILD ALLERGY RLF 30 MG/5, CHILD CETIRIZINE 10 MG CHEW TB, CHILD CETIRIZINE 5 MG CHEW TAB, CHILDREN'S WAL-FEX, CHILD'S WAL-ZYR 10 MG CHEW TAB, CHILDREN'S ZYRTEC ALLERGY, CLARITIN 10 MG LIQUI-GEL CAP, CLARITIN 10 MG REDITABS, CLARITIN 5 MG REDITABS, CLARITIN-D 24 HOUR, FEXOFENADINE HCL 180 MG TABLET, FEXOFENADINE HCL 30 MG/5 ML, FEXOFENADINE HCL 60 MG TABLET, HM FEXOFENADINE HCL 180 MG TAB, HM FEXOFENADINE HCL 60 MG TAB, QC FEXOFENADINE HCL 180 MG TAB, SM FEXOFENADINE HCL 180 MG TAB, SM FEXOFENADINE HCL 60 MG TAB, FEXOFENADINE-PSE ER, LEVOCETIRIZINE 2.5 MG/5 ML SOL, LEVOCETIRIZINE 5 MG TABLET, LORATA-D, LORATA-DINE D, LORATADINE 10 MG ODT, LORATADINE 10 MG SOFTGEL, LORATADINE-D, WAL-FEX ALLERGY, WAL-FEX D 12 HOUR, WAL-FEX D 24 HOUR, WAL-ITIN D, WAL-ITIN D 12 HOUR, WAL-ZYR 10 MG SOFTGEL, WAL-ZYR D, XYZAL, ZYRTEC 10 MG LIQUID GELS, ZYRTEC 10 MG ODT, ZYRTEC-D

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Coverage for Medicaid 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

1. Confirmed diagnosis of allergic rhinitis, allergic conjunctivitis, or chronic rhinitis/pharyngitis/nasopharyngitis
2. Confirmed diagnosis of one of the following co-morbidities:
a. Asthma or reactive airway disease exacerbated by chronic/allergic rhinitis or allergies
i. Patient must be using an asthma controller medication (e.g. inhaled corticosteroid, leukotriene antagonist, and/or inhaled rescue beta-agonist) within the previous six (6) months
b. Acute or chronic inflammation of the orbit
c. Chronic sinusitis
d. Acute sinusitis
e. Sleep apnea
f. Wegener's Granulomatosis
AND
3. For non-preferred products: Documented trial and failure*, intolerance or contraindication to preferred products (e.g., cetirizine tablets/solution AND loratadine tablet/syrup). *Trial and failure is defined as at least one month of therapy with insufficient response.

AGE RESTRICTION
Please see specific product information for age restrictions.

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A

SGLT-2 INHIBITORS - MEDICAID

MEDICATION(S)
FARXIGA, INVOKAMET, INVOKAMET XR, INVOKANA, JARDIANCE, SEGLUROMET, STEGLATRO, SYNJARDY, SYNJARDY XR, XIGDUO XR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For type 2 diabetes, empagliflozin (Jardiance/Synjardy/Synjardy XR®) and dapagliflozin (Farxiga/Xigduo XR®) will be covered with trial (history of paid claim), intolerance, or contraindication to metformin. For all other SGLT-2 agents, all of the following criteria must be met:
1. Documentation of trial and failure, contraindication or intolerance to metformin therapy at the maximum effective dose of 2000 mg/day. Trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy.
AND
2. Documentation of a trial and failure, contraindication or intolerance to empagliflozin and dapagliflozin. Trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy.
AND
3. A documented HbA1c, obtained within the last six months, which is greater than or equal to 7% and less than or equal to 10%.

For heart failure (with or without diabetes), dapagliflozin may be covered if the following criteria are met:
1. Documented diagnosis of heart failure with reduced ejection fraction (HFrEF) with New York Heart Association (NYHA) functional class II-IV
2. Documented left ventricular ejection fraction of less than or equal to 40% that has been present for at least 2 months

For chronic kidney disease (with or without diabetes), dapagliflozin may be covered in adult patients if the following criteria are met:
1. Patient has a documented current estimated glomerular filtration rate (eGFR) of at least 25, but less than or equal to 75 mL/min/1.73m2 (using CKD-EPI Formula)
2. Urinary albumin-to-creatinine ratio (UACR) of at least 200 and less than or equal to 5000 mg/g
3. Patient is currently taking a stable dose (at least 4 weeks) of maximum tolerated daily dose of one of the

following, or intolerance/contraindication to both classes
a. Angiotensin converting enzyme (ACE) inhibitor
b. Angiotensin receptor blocker (ARB)
4. Patient does not have any of the following: Autosomal dominant or autosomal recessive polycystic kidney disease, lupus nephritis, or anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis

For chronic kidney disease, canagliflozin may be covered if the following criteria are met
1. Patient has type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day.
2. Documented trial, intolerance or contraindication to dapagliflozin

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

SIGNIFOR LAR - MEDICAL BENEFIT

MEDICATION(S)
SIGNIFOR LAR

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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 endocrinologist

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

OTHER CRITERIA
Treatment of patients with acromegaly:
1. Documentation that the patient has persistent, moderate-to-severe symptoms of acromegaly (e.g., impaired glucose tolerance, hypertension, elevated triglycerides, arrhythmias) following surgical resection, or patient is ineligible for surgery
AND
2. Documentation of trial and failure, intolerance or contraindication to octreotide injection therapy

Note: Mild symptoms of disease are typically treated with a dopamine agonist (e.g., cabergoline)

Patients with Cushing's disease:
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:
Acromegaly: documentation of response to therapy, as defined as normalization of insulin-like growth factor (IGF)-1 and reduction of symptoms

Cushing’s disease: 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)

SOLIRIS - MEDICAL BENEFIT

MEDICATION(S)
SOLIRIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Paroxysmal Nocturnal Hemoglobinuria (PNH), all of the following must be met:
1. Documented, confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glychophosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)
AND
2. Severe disease as indicated by at least one of the following (a or b):
a. Documented history of thrombosis, OR
b. Documentation of at least 10% PNH type III red cells AND at least one (1) of the following:
i. Transfusion dependence (eg. hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
ii. Disabling fatigue
iii. End-organ complications
iv. Frequent pain paroxysms (eg. dysphagia or abdominal pain)
v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal
AND
3. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for PNH:
1. Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms
2. Dose and frequency is in accordance with FDA-approved labeling

For Compliment-Mediated Hemolytic Uremic Syndrome (HUS), all of the following must be met:
1. Diagnosis of non-infectious HUS (i.e. HUS is not due to infection with Shiga toxin-producing Escherichia coli)

AND
2. Clinical presentation that includes: microangiopathic hemolytic anemia (hemoglobin less than 10 g/dL), thrombocytopenia (platelets less than 150), and acute kidney injury (elevations in serum creatinine)
AND
3. Compliment dysregulation confirmed by genetic testing (e.g., mutations in complement regulatory genes: factor H (CFH), membrane cofactor protein (CD46), factor I (CFI), thrombomodulin (THBD), the activatory genes: factor B (CFB) and C3 and autoantibodies to CFH)
AND
4. Prior or current treatment with plasma therapy (plasmapheresis or plasma infusions) OR medical rationale of why plasma therapy is not appropriate for member
AND
5. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for HUS:
1. Documentation of improvement in at least two thrombotic microangiopathy endpoints, such as:
• Maintenance of platelet counts (i.e. improvements or reductions less than 25%)
• Reductions in LDH
• Reduction in number of needed plasmaphoresis or plasma infusion events
• Improvement in kidney function and reduction of dialysis
2. Dose and frequency is in accordance with FDA-approved labeling

For Generalized Myasthenia Gravis (gMG), all of the following must be met:
1. Anti-acetylcholine receptor (anti-AChR) antibody positive
AND
2. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
AND
3. Myasthenia Gravis -Activities of Daily Living (MG-ADL) total score greater than 5
AND
4. Failed treatment for at least one (1) year with the following:
A. At least TWO (2) immunosuppressive therapies ([ISTs] such as azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus,corticosteroids)
OR
B. ONE (1) immunosuppressive therapy and required at least four (4) infusions/ year of either intravenous immunoglobulin (IVIg) OR plasma exchange (PE)
AND
5. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for Myasthenia Gravis (MG):
1. Initial reauthorization may require documentation of improvement in MG-ADL by at least two (2) points from baseline.

2. Dose and frequency is in accordance with FDA-approved labeling

For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:
1. Diagnosis of neuromyelitis optica spectrum disorder as defined as the following:
A. Presence of at least one (1) core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions)
AND
B. Anti-AQP4 antibody positive
AND
2. Documentation that other alternative diagnoses have been excluded (i.e. Multiple Sclerosis)
AND
3. Trial and failure, intolerance or contraindication to rituximab
AND
4. Medication will not be used in combination with complement inhibitor (e.g.ravulizumab-cwvz), anti-CD20-directed (e.g., rituximab), anti-CD19 directed (e.g., inebilizumab) or IL-6 inhibition pathway therapies (e.g., satralizumab)
AND
5. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for Neuromyelitis Optica Spectrums Disorder (NMOSD):
1. Documentation of positive clinical response to therapy
2. Medication will not be used in combination with complement inhibitor (e.g.ravulizumab-cwvz), anti-CD20-directed (e.g., rituximab), anti-CD19 directed (e.g., inebilizumab) or IL-6 inhibition pathway therapies (e.g., satralizumab)
3. Dose and frequency is in accordance with FDA-approved labeling

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PNH or aHUS: Prescribed by an hematologist/oncologist or nephrologist
MG or NMOSD: Prescribed by a neurologist

COVERAGE DURATION
Initial authorization for up to three (3) months and reauthorization will be approved for up to one year.

OTHER CRITERIA
N/A

SOMAVERT

MEDICATION(S)
SOMAVERT

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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 inadequate 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

SPINRAZA - MEDICAL BENEFIT

MEDICATION(S)
SPINRAZA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
1. Concomitant use with, or following, gene therapy for SMA (e.g., onasemnogene abeparvovec)
2. Advanced symptoms of SMA (e.g., complete paralysis of limbs, tracheostomy or ongoing invasive ventilator support in the absence of an acute reversible illness)

REQUIRED MEDICAL INFORMATION
For initial authorization, all of the following criteria must be met:
1. Confirmed genetic diagnosis of SMA with documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and less than or equal to 3 copies of SMN2
AND
2. Patient is presymptomatic or has symptoms with an onset at age less than 30 years
AND
3. Documentation of baseline motor function, with a standardized test appropriate based on the patient's age and level of function: CHOP-INTEND, HINE, HFMSE, RULM, or 6MWT

NOTE the following guidance on selecting an appropriate test:
• Non-sitters (infants and kids): CHOP-INTEND, HINE (may need HFSME as they transition to sitting).
• Sitters: HFSME, RULM
• Walkers (kids): 6WWT, HFSME
• Walkers (adults): 6MWT, RULM
• Non-walkers (adults): RULM

CHOP-INTEND: Children's hospital of Philadelphia Infant Test of Neuromuscular Disorders
HINE: Hammersmith Infant Neurological Examination
HFSME: Hammersmith Functional Motor Scale Expanded
6MWT: six-minute walk test
RULM: Revised Upper Limb Module

For reauthorization: Improvement or maintenance of motor function, evidenced by stabilization or improvement in motor function test scores performed at baseline

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist

COVERAGE DURATION

Initial authorization and reauthorization will be approved for 12 months.

OTHER CRITERIA

N/A

STRENSIQ

MEDICATION(S)
STRENSIQ

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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 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 16 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 disease within the past year
b. Chronic sinusitis

c. Acute sinusitis
d. Sleep apnea

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

OTHER CRITERIA
N/A

SUCRAID

MEDICATION(S)
SUCRAID

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of secondary (acquired) disaccharide deficiencies

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Diagnosis of congenital sucrase-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 greater than 25 mcM/min/g]
b. A positive genetic test for a pathogenetic mutation in the sucrase-isomaltase (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 six (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 sucrase-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 continue to be given in conjunction with dietary limitation of sucrose and starch intake

AGE RESTRICTION
N/A

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

COVERAGE DURATION

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

OTHER CRITERIA

N/A

SYLVANT - MEDICAL BENEFIT

MEDICATION(S)
SYLVANT

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization:
1. Confirmed diagnosis of Multicentric Castleman Disease (MCD)
AND
2. Documentation of negative human immunodeficiency virus (HIV) status
AND
3. Documentation of negative human herpes-virus 8 (HHV-8) status

Reauthorization will require positive response to therapy as well as documentation that patient remains HIV and HHV-8 negative.

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
N/A

SYMLINPEN

MEDICATION(S)
SYMLINPEN 120, SYMLINPEN 60

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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
Seizure disorders

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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)

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

SYPRINE

MEDICATION(S)
CLOVIQUE, SYPRINE, TRIENTINE HCL

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
Cystinuria or rheumatoid arthritis

REQUIRED MEDICAL INFORMATION
Documentation of severe or intolerable adverse effects to penicillamine tablet (Depen®)

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
N/A

TAFAMIDIS

MEDICATION(S)
VYNDAMAX, VYNDAQEL

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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 (Onpattro®), inotersen (Tegsedi®)

REQUIRED MEDICAL INFORMATION
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

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
N/A

TAVALISSE

MEDICATION(S)
TAVALISSE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Diagnosis of chronic immune thrombocytopenia (ITP)
2. Platelet count of less than 30,000 cells/microliter
3. Inadequate response to at least TWO of the following therapies:
a. Corticosteroids
b. Immunoglobulins
c. Splenectomy
d. Thrombopoietin receptor agonists
e. Rituximab

Reauthorization:
1. Documentation of an improvement in platelet count to 50,000 cells/microliter or greater

QUANTITY LIMIT:
Fostamatinib Disodium (Tavalisse®) 100 and 150 mg tablets: 2 per day

AGE RESTRICTION
Approved for 18 years of age and older.

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

COVERAGE DURATION
Initial authorization for 3 months and reauthorization for 1 year.

OTHER CRITERIA
N/A

TEPEZZA

MEDICATION(S)
TEPEZZA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met:
1. Confirmed diagnosis of moderate-to-severe thyroid eye disease/Grave's Orbitopathy, as defined by one (1) of the following:
a. Sight-threatening disease (e.g., dysthyroid optic neuropathy, corneal breakdown)
b. Eye disease significantly impacts quality of life and at least two of the following:
i. Lid retraction of at least 2 mm, marginal reflex distance-1 (MRD1) greater than 4, or presence of lagophthalmos
ii. Moderate or severe soft-tissue involvement (e.g. swelling or redness of the eyes)
iii. Inconstant diplopia (i.e., diplopia at extremes of gaze) or constant diplopia (i.e., continuous diplopia in primary or reading position)
2. Documentation of active disease, defined as a Clinical Activity Score of at least three (3)
3. Laboratory evidence of euthyroid state
4. Inadequate response to at least two weeks of therapy with high-dose intravenous (IV) glucocorticoid therapy (equivalent to methylprednisolone 0.5 g once weekly) or inability to use this therapy (e.g., evidence of recent viral hepatitis, significant hepatic dysfunction, severe cardiovascular morbidity or psychiatric disorders)

Reauthorization is not considered medically necessary and will not be covered.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Authorization will be approved for six (6) months for a total of eight (8) infusions

OTHER CRITERIA

N/A

TESTOSTERONE REPLACEMENT THERAPY (TRT)

MEDICATION(S)
ANDRODERM, ANDROGEL 1.62% GEL PUMP, ANDROGEL 1.62%(1.25G) GEL PCKT, ANDROGEL 1.62%(2.5G) GEL PCKT, AVEED, FORTESTA, JATENZO, NATESTO, STRIANT, TESTOPEL, TESTOSTERONE 1.62% (2.5 G) PKT, TESTOSTERONE 1.62% GEL PUMP, TESTOSTERONE 1.62%(1.25 G) PKT, TESTOSTERONE 10 MG GEL PUMP, TESTOSTERONE 30 MG/1.5 ML PUMP, XYOSTED

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
Use for improvement of sexual signs and symptoms (e.g., decreased libido, sexual dysfunction)

Medicaid only:
The procedure to implant Testopel® is not a covered benefit and therefore, the drug itself will not be covered

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 annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
For patients established on testosterone replacement therapy:
1. Documented trial and failure of generic topical testosterone 1%. Failure is defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms

For initiation of testosterone replacement therapy, all of the following criteria must be met:

1. Documentation of trial and failure, contraindication or intolerance to generic topical testosterone 1%. Failure is defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms, AND
2. One of the following:
a. Diagnosis of gender dysphoria or gender identity disorder
OR
b. Diagnosis of primary or secondary (hypogonadatropic) hypogonadism, AND confirmatory laboratory values, as outlined below, taken before 11 am, or within 3 hours of waking for shift-workers, on different days without acute illness/stress, according to the local laboratory's lower limit of normal (if available) or levels according to the listed values below:
i. At least two (2) serum total testosterone levels less than 264 ng/dL (9.2 nmol/L) OR
ii. At least two (2) free testosterone levels less than 2 ng/dL (20 pg/mL) OR
iii. At least one (1) serum total testosterone level less than 264 ng/dL (9.2 nmol/L) AND one (1) free testosterone levels less than 2 ng/ dL (20 pg/mL). Serum total testosterone level and free testosterone level must be taken on different days

THERAPEUTIC IMMUNOMODULATORS (TIMS)- MEDICAID

MEDICATION(S)

ACTEMRA, ACTEMRA ACTPEN, AVSOLA, CIMZIA, COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE, ENBREL, ENBREL MINI, ENBREL SURECLICK, ENTYVIO, 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 PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS, ILUMYA, INFLECTRA, KEVZARA, KINERET, OLUMIANT, ORENCIA, ORENCIA CLICKJECT, OTEZLA, REMICADE, RENFLEXIS, RINVOQ, SILIQ, SIMPONI, SIMPONI ARIA, SKYRIZI (2 SYRINGES) KIT, STELARA, TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE, TREMFYA, XELJANZ, XELJANZ XR

COVERED USES

N/A

EXCLUSION CRITERIA

1. Below the line diagnoses
2. Combination therapy with another therapeutic immunomodulator (TIM) agent or apremilast (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 is a covered indication according to the Prioritized List of Health Care Services.

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. For Hidradenitis Suppurativa, continuation of adalimumab therapy may be covered with clear evidence of response, defined as BOTH of the following:

1. A reduction of 25% or more in the total abscess and inflammatory nodule count, AND
2. No increase in abscesses and draining fistulas

ii. For all other indications: 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 rheumatoid arthritis:
1. Use of disease-modifying anti-rheumatic drugs (DMARDs):
a. Documented inadequate response to at least one DMARD after at least 6 months of therapy: methotrexate, leflunomide, sulfasalazine or hydroxychloroquine
OR
b. Documented intolerance or contraindication to all DMARDs (i.e., methotrexate, leflunomide, sulfasalazine and hydroxychloroquine)
2. For non-preferred TIMs agent:
a. Documented adequate trial and failure (after at least 3 months of therapy), intolerance or contraindication to at least one of the following preferred TIMs agents: adalimumab (Humira®), etanercept (Enbrel®), or infliximab biosimilar (Inflectra®, Renflexis®, Avsola®)
ii. For inflammatory bowel diseases (e.g. Crohn's disease, ulcerative colitis):
1. Use of conventional immunosuppressive therapies:
a. Documented inadequate response to at least one of the following conventional immunosuppressive therapies for at least 6 months: mercaptopurine, azathioprine, or budesonide
OR
b. Documented intolerance or contraindication to these therapies
OR
c. Medical rationale is provided for escalating to biologic therapy without previous trial of conventional therapies (e.g., severity of disease activity)
2. For non-preferred TIMs agent:
a. Documented adequate trial and failure (after at least 3 months of therapy), intolerance or contraindication to at least two of the following TIMs agents: adalimumab (Humira®), infliximab biosimilar (Inflectra®, Renflexis®, Avsola®) or vedolizumab (Entyvio®).
iii. For psoriasis:
1. Member must have severe disease, as defined as having functional impairment (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) AND at least one of the following:
a. At least 10% of body surface area involved
b. Hand, foot or mucous membrane involvement
2. Documented adequate trial and failure (after at least 3 months of therapy), intolerance or contraindication to each of the following first-line agents:
a. Topical high-potency corticosteroids (e.g., betamethasone 0.05%, clobetasol 0.05%, fluocinonide 0.05%, halcinonide 0.1%, halobetasol propionate 0.05%, triamcinolone 0.5%)
b. Another topical agent (e.g., calcipotriene, tazarotene)
c. Phototherapy
d. Systemic therapy (e.g., methotrexate, cyclosporine)
3. For non-preferred TIMs agent: Documented adequate trial and failure (after at least 3 months of therapy),

intolerance or contraindication to the following preferred agents:
a. One of the following TNF inhibitor agents: adalimumab (Humira®)or infliximab biosimilar (Inflectra®, Renflexis®, Avsola®)
AND
b. Secukinumab (Cosentyx®)
iv. For psoriatic arthritis:
1. Documented inadequate response to at least 3 months of therapy with at least two non-steroidal anti-inflammatory agents (e.g., etodolac, nabumetone, meloxicam), unless skin lesions are also present or the patient has a contraindication or intolerance.
2. Documented inadequate response to at least one DMARD after at least 6 months of therapy (e.g., methotrexate, leflunomide, sulfasalazine or hydroxychloroquine) unless contraindicated or not tolerated
3. For non-preferred TIMs agent: Documented adequate trial and failure (after at least 3 months of therapy), intolerance or contraindication to the following preferred agents:
a. One the following agents: adalimumab (Humira®), etanercept (Enbrel®) or infliximab biosimilar (Inflectra®, Renflexis®, Avsola®)
AND
b. If patient has satisfied criteria above (iv.3.a.), documented trial and failure (after at least 3 months of therapy), intolerance or contraindication to one of the following: apremilast (Otezla®) or tofacitinib (Xeljanz XR®)
v. For ankylosing spondylitis:
1. For non-preferred TIMs agent: Documented trial and failure (after at least 3 months of therapy), intolerance or contraindication to at least one of the following preferred agents: adalimumab (Humira®), etanercept (Enbrel®) or infliximab biosimilar (Inflectra®, Renflexis®, Avsola®)
vi. For Non-radiographic axial spondyloarthritis:
1. For non-preferred TIMS agent: Documentation trail and failure (after at least 3 months of therapy), intolerance or contraindication to certolizumab (Cimzia®)
vii. For giant cell arteritis, tocilizumab (Actemra®) may be covered with documentation of trial and failure (after at least 3 months of therapy), intolerance, or contraindication to at least one conventional therapy (e.g., systemic corticosteroid therapy)
viii. For Hidradenitis Suppurativa, adalimumab (Humira®) may be covered if the following criteria are met:
1. Documentation of moderate to severe disease (e.g. Hurley Stage II or Hurley Stage III)
2. Documented inadequate response to at least one conventional therapy after 90 days of therapy (e.g., oral antibiotics) unless contraindicated or not tolerated
Note:
• Conventional therapy requirements may be waived if the patient has previously used another therapeutic immunomodulator agent
• Conventional therapy and preferred agent requirements may be waived with clinically appropriate medical rationale

For quantity limit exception requests(See Appendix 1 for specific quantity limits)

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 therapy with oral disease modifying anti-rheumatic (DMARD) therapy (e.g., methotrexate, leflunomide, sulfasalazine) in combination with the requested TIMs agent for at least six (6) months is also required, unless there are contraindications to their use
e. Exceptions:
i. For Hidradenitis Suppurativa: once weekly dosing of Humira® will be approved
ii. For Crohn's Disease and Ulcerative Colitis, Stelara® may be approved for FDA labeled dosing for this condition (90 mg every 8 weeks). Dosing of Stelara® more frequently is considered experimental and investigational and is not covered.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a specialist for the respective indication, such as:
• Rheumatoid arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis: rheumatologist
• Psoriasis and Hidradenitis Suppurativa: dermatologist
• Psoriatic arthritis: dermatologist or rheumatologist
• Inflammatory Bowel Disease: gastroenterologist
• Giant Cell Arteritis: rheumatologist or neurologist

COVERAGE DURATION
• Prior Authorization: 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. Reauthorization will be approved for one year.
o Exception: Authorization for every 8 week dosing of ustekinumab (Stelara®) for Crohn's or 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
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.

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
N/A

TOLVAPTAN

MEDICATION(S)
JYNARQUE, SAMSCA, TOLVAPTAN

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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)

TOTAL PARENTAL NUTRITION (TPN)

MEDICATION(S)

AMINOSYN, AMINOSYN II, AMINOSYN M, AMINOSYN 7%-ELECTROLYTE SOL, AMINOSYN-HBC, AMINOSYN-PF, AMINOSYN-RF, CLINIMIX, CLINIMIX E, CLINIMIX N14G30E, CLINIMIX N9G15E, CLINIMIX N9G20E, CLINISOL, CLINOLIPID, FREAMINE HBC, FREAMINE III, HEPATAMINE, INTRALIPID, NEPHRAMINE, NUTRILIPID, OMEGAVEN, PLENAMINE, PREMASOL, PROCALAMINE, PROSOL, SMOFLIPID, SYNTHAMIN 17 WITHOUT ELTYE, TRAVASOL, TROPHAMINE

COVERED USES

N/A

EXCLUSION CRITERIA

Coverage for intradialytic parenteral nutrition (IDPN) when offered in addition to regularly scheduled TPN infusions

REQUIRED MEDICAL INFORMATION

One of the following criteria must be met:

1. Member has a central or peripheral line and nutrition will be administered via this line.

OR

2. Documentation of a failure to enteral nutrition (either oral or via tube), defined as either a or b:

a. A documented loss of at least 10% of body weight over a three-month period

b. Member is unable to reach nutritional needs from combined oral and enteral intake (less than 75 percent of estimated basal caloric requirements)

OR

3. Evidence of structural or functional bowel disease (e.g. massive small bowel resection, short bowel syndrome) that makes oral and tube feedings not possible

OR

4. A condition in which it is necessary for the gastrointestinal tract to be totally non-functioning for a period of time (i.e. bowel rest)

Medically necessary intradialytic parenteral nutrition (IDPN) may be covered for members on chronic dialysis who meet criteria 2, 3 or 4 AND cannot tolerate daily TPN.

For continued coverage, annual assessment that documents the ongoing medical necessity of PN as per the above criteria will be required.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization will be approved for 3 months and reauthorization will be approved for up to one year.

OTHER CRITERIA

N/A

TRANSTHYRETIN (TTR) LOWERING AGENTS

MEDICATION(S)
ONPATTRO, TEGSEDI

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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
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 than 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:
3. Baseline polyneuropathy disability (PND) score
4. Familial amyloid polyneuropathy (FAP) stage
5. 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

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
N/A

TROGARZO/RUKOBIA - MEDICAL BENEFIT

MEDICATION(S)
RUKOBIA, TROGARZO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization:
1. Inadequate response to six (6) months of treatment with anti-retroviral therapy (ART) and have failed therapy within the last eight (8) weeks
a. Defined as persistent viremic failure
b. Failure must not be due to non-adherence (adherence may be verified by pharmacy claims)
2. Documentation of multi-drug resistant human immunodeficiency virus (HIV)-1 infection with viral resistance to at least one antiretroviral medication from each of the three (3) following classes:
a. Non-nucleoside reverse transcriptase inhibitor
b. Nucleoside reverse transcriptase inhibitor
c. Protease inhibitor
3. Documentation of baseline viral load
4. Confirmation that patient will take an optimized background regimen of anti-retroviral therapy (ART) along with Trogarzo™ or Rukobia™ therapy

Re-authorization or continuation of therapy:
1. Patient has previously received treatment with Trogarzo™.
2. Documentation of a clinically significant decrease in viral load from baseline (prior to starting therapy)
3. Confirmation that patient will continue to take an optimized background regimen of anti-retroviral therapy (ART) with Trogarzo™ or Rukobia™ therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an infectious disease specialist.

COVERAGE DURATION
Initial authorization will be approved for 6 months and reauthorization will be approved for one (1) year.

OTHER CRITERIA

N/A

TYMLOS

MEDICATION(S)
TYMLOS

COVERED USES
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit, and for use in men

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)

TYSABRI - MEDICAL BENEFIT

MEDICATION(S)
TYSABRI

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
Use of Tysabri® in combination with other disease modifying therapy to treat patients with multiple sclerosis will not be covered.
In Crohn's disease, the use of Tysabri® in combination with immunosuppressants or inhibitors of TNF-? will not be covered.

REQUIRED MEDICAL INFORMATION
For Multiple Sclerosis:
1. One of the following:
a. Documentation of trial, failure, or intolerance to at least two of the following disease modifying therapies:
i. Interferon therapy (Avonex®, Rebif®Plegridy®, or Betaseron®)
ii. dimethyl fumarate (Tecfidera®)
iii. glatiramer acetate (Copaxone®)
iv. teriflunomide (Aubagio®)
v. fingolimod (Gilenya®)
vi. ocrelizumab (Ocrevus®)
vii. diroximel fumarate (Vumerity®)
viii. ozanimod hydrochloride (Zeposia®)
ix. siponimod (Mayzent®)
OR
b. Documentation that patient has highly active or aggressive disease
AND
2. Negative anti-JCV antibody status OR if anti-JCV antibody positive, the patient must meet the following criteria:
a. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, or mycophenolate mofetil
AND
b. Medical rationale is provided for continued use despite increased risk of developing progressive multifocal leukoencephalopathy (PML)
For Crohn's disease:
1. Diagnosis of moderate to severe Crohn's disease

AND
2. Documentation of trial, failure, intolerance, or lack of response to a formulary TNF-? inhibitor (Remicade® and/or Humira®) indicated for Crohn’s
AND
3. Negative anti-JCV antibody status OR if anti-JCV antibody positive, the patient must meet the following criteria:
a. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, and mycophenolate mofetil
AND
b. Medical rationale is provided for continued use despite increased risk of developing progressive multifocal leukoencephalopathy (PML)

For reauthorization: Documentation of response to therapy must be provided

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by either a neurologist or gastroenterologist

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

OTHER CRITERIA
N/A

UCERIS

MEDICATION(S)
BUDESONIDE ER, UCERIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For budesonide extended release tablets (Uceris®)
For mild to moderate, active ulcerative colitis:
1. Confirmed diagnosis of mild to moderate, active ulcerative colitis
AND
2. Documented trial, failure, intolerance or contraindication to treatment with an aminosalicylate (e.g., sulfasalazine, mesalamine)
AND
3. Documented trial, failure, intolerance or contraindication to one of the following oral corticosteroids: dexamethasone, hydrocortisone, methylprednisolone, prednisone or budesonide extended release capsule

For microscopic colitis:
1. Confirmed diagnosis of active, microscopic colitis

For budesonide foam (Uceris®):
For mild to moderate, active ulcerative colitis:
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 will allow for an 8-week treatment course. Further approval for Uceris® requires medical rationale why additional treatment is warranted for ulcerative colitis and microscopic colitis and if patient is not on maintenance therapy for ulcerative colitis why it is not appropriate.

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

N/A

ULTOMIRIS

MEDICATION(S)
ULTOMIRIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Paroxysmal Nocturnal Hemoglobinuria (PNH):
Initial authorization all of the following must be met:
1. Confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two (2) independent flow cytometry reagents on at least two (2) cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glychophosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)
AND
2. Severe disease as indicated by at least one of the following (a or b):
a. Documented history of thrombosis, OR
b. Documentation of at least 10% PNH type III red cells AND at least one of the following:
i. Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
ii. Disabling fatigue
iii. End-organ complications
iv. Frequent pain paroxysms (e.g., dysphagia or abdominal pain)
v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal
AND
3. Dose and frequency is in accordance with FDA-approved labeling

For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®) for PNH:
1. Confirmed documentation of paroxysmal nocturnal hemoglobinuria (criteria 1 above) and severe disease (criteria 2 above). However, this can be based on patient's history prior to starting eculizumab.
AND
2. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization:

1. Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms
2. Dose and frequency is in accordance with FDA-approved labeling

Compliment-Mediated Hemolytic Uremic Syndrome (HUS)
Initial authorization all of the following must be met:
1. Diagnosis of non-infectious HUS (i.e. HUS is not due to infection with Shiga toxin-producing Escherichia coli)
AND
2. Clinical presentation that includes: microangiopathic hemolytic anemia (hemoglobin less than 10 g/dL), thrombocytopenia (platelets less than 150), and acute kidney injury (elevations in serum creatinine)
AND
3. Compliment dysregulation confirmed by genetic testing (e.g., mutations in complement regulatory genes: factor H (CFH), membrane cofactor protein (CD46), factor I (CFI), thrombomodulin (THBD), the activator genes: factor B (CFB) and C3 and autoantibodies to CFH)
AND
4. Prior or current treatment with plasma therapy (plasmapheresis or plasma infusions) OR medical rationale of why plasma therapy is not appropriate for member
AND
5. Dose and frequency is in accordance with FDA-approved labeling

For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®)
1. Confirmed documentation of Compliment-Mediated Hemolytic Uremic Syndrome (criteria 1, 2 and 3 above). However, this can be based on patient's history prior to starting eculizumab.
AND
2. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for HUS:
1. Documentation of improvement in at least two thrombotic microangiopathy endpoints, such as:
• Maintenance of platelet counts (i.e. improvements or reductions less than 25%)
• Reductions in LDH
• Reduction in number of needed plasmaphoresis or plasma infusion events
• Improvement in kidney function and reduction of dialysis
2. Dose and frequency is in accordance with FDA-approved labeling

AGE RESTRICTION
For PNH: Approved for 18 years of age and older
For aHUS: No age restriction

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a nephrologist, hematologist or an oncologist

COVERAGE DURATION

Initial authorization for up to 3 months and reauthorization will be approved for up to one year.

OTHER CRITERIA

N/A

UPLIZNA

MEDICATION(S)
UPLIZNA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:
1. Diagnosis of neuromyelitis optica spectrum disorder as defined as the following:
a. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions)
AND
b. Anti-AQP4 antibody positive
2. Documentation that other alternative diagnoses have been excluded (i.e. Multiple Sclerosis)
3. Trial and failure, intolerance or contraindication to rituximab
4. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
5. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for Neuromyelitis Optica Spectrum Disorder (NMOSD):
1. Documentation of positive clinical response to therapy
2. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
3. Dose and frequency is in accordance with FDA-approved labeling

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by a neurologist

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

OTHER CRITERIA

N/A

UPNEEQ

MEDICATION(S)
UPNEEQ

COVERED USES
N/A

EXCLUSION CRITERIA
• Congenital ptosis
• Horner syndrome
• Myasthenia gravis
• Mechanical ptosis
• Visual field loss from any cause other than ptosis

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. Documentation of acquired blepharoptosis,
2. Documentation of a superior visual field deficit [e.g., inability to detect at least 8 of 17 points in the top two (2) rows on the Leicester Peripheral Field Test (LPFT)],
3. Marginal reflex distance 1 (MRD-1) of less than or equal to two (2) mm.

Reauthorization requires documentation of improvement in visual field deficit

QUANTITY LIMIT:
One (1) droperette per day

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be approved for six (6) months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA
N/A

VASCEPA

MEDICATION(S)
ICOSAPENT ETHYL, VASCEPA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Hypertriglyceridemia all of the following must be met:
1. Trial and failure (defined as at least two (2) months of therapy), intolerance, or contraindication to one of the following formulary agents to treat very high triglycerides: fenofibrate or gemfibrozil.
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.

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

VEREGEN

MEDICATION(S)
VEREGEN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented trial, failure, intolerance, or contraindication to imiquimod 5% cream packets (Aldara®).

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
N/A

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 two (2) of the following drug classes:

a. Anti-spasmodic agent [e.g., dicyclomine (Bentyl®)]
b. Tricyclic antidepressants [e.g., amitriptyline (Elavil®)]
c. Opioid mu receptor agonists [e.g., loperamide (Imodium®), diphenoxylate (Lomotil®)]

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
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved for 1 month.

OTHER CRITERIA
N/A

VMAT2 INHIBITORS

MEDICATION(S)

AUSTEDO, INGREZZA, INGREZZA INITIATION PACK, TETRABENAZINE, XENAZINE

COVERED USES

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

VYLEESI

MEDICATION(S)
VYLEESI

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
• Uncontrolled hypertension
• Known cardiovascular 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 patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an obstetrician, gynecologist, urologist, and/or women's health nurse practitioner

COVERAGE DURATION
Initial authorization will be approved for 8 weeks and reauthorization will be approved for 1 year

OTHER CRITERIA
For initial authorization, must meet ALL of the following criteria:
1. Patient is female and premenopausal
AND
2. Diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
a. A co-existing medical or psychiatric condition
b. Problems within the relationship
c. The effects of a medication or drug substance

Reauthorization requires documentation that the patient continues to be pre-menopausal and has had a positive response to the medication

QUANTITY LIMIT:
Four (4) auto injectors per 30 days

WAKIX

MEDICATION(S)
WAKIX

COVERED USES
N/A

EXCLUSION CRITERIA
Idiopathic central nervous system hypersomnia

REQUIRED MEDICAL INFORMATION
Initial Authorization:
For excessive daytime sleepiness with narcolepsy, the following criteria must be met:
1. 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)
2. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three (3) months
3. 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)
4. Documentation of a three (3)-month trial and failure, incomplete response, intolerance, or contraindication to both of the following:
a. Stimulant (e.g., amphetamine, methylphenidate)
b. Modafinil or armodafinil
For cataplexy in adult patients with narcolepsy, the following criteria must be met:
1. 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)
2. Documentation of excessive daytime sleepiness defined as an Epworth Sleepiness Scale (ESS) score more than or equal to 12 or documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three (3) months
3. Documentation of at least three (3) weekly cataplexy attacks

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:

Two (2) tablets per day

AGE RESTRICTION

May be covered for patients 18 years or older

PRESCRIBER RESTRICTION

Must be prescribed by a sleep specialist, neurologist, pulmonologist, or psychiatrist.

COVERAGE DURATION

Initial authorization approved for 6 months. Reauthorization approved for 12 months.

OTHER CRITERIA

N/A

XERMELO

MEDICATION(S)
XERMELO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met:
1. Diagnosis of carcinoid syndrome diarrhea
2. Patient is experiencing four (4) or more bowel movements per day, despite use of long-acting somatostatin analog therapy, such as octreotide LAR (Sandostatin LAR®) or lanreotide (Somatuline®), for at least three (3) months
3. Documentation of trial and failure of both of the following agents for breakthrough symptoms: loperamide and short-acting octreotide (Sandostatin®)
4. Documentation that long-acting somatostatin analog therapy will be used in combination with the requested medication

Reauthorization will require documentation of positive clinical response to therapy

AGE RESTRICTION
Age 18 years or older

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

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

OTHER CRITERIA
N/A

XHANCE

MEDICATION(S)
XHANCE

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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, an Allergist, pulmonologist or Head and Neck Surgeon (Ear Nose and Throat [ENT] specialist).

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

OTHER CRITERIA
1. Diagnosis of nasal polyps
2. Documented trial, failure, intolerance or contraindication to three (3) nasal steroids (e.g., fluticasone propionate, mometasone, budesonide)

XIAFLEX

MEDICATION(S)
XIAFLEX

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Dupuytren's contracture:
1. Both of the following diagnostic criteria:
a. Finger flexion contracture with a palpable cord of at least one finger (other than the thumb) of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint
b. Documentation of a positive "table top test," defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top
2. Documentation that affected joint has not had surgical intervention within the previous 90 days

For Peyronie's disease:
1. Patient's disease is stable, defined as unchanged degree of curvature for at least three months
2. Patient has a stable curvature of the penis that is between 30 and 90 degrees with a palpable plaque cord, or a cord that is documented through ultrasound
3. Patient has intact erectile function, with or without the use of medications
4. Documentation of a functional impairment that is expected to improve with treatment (e.g. inability to have intercourse despite intact erectile function, due to curvature)
5. Documentation showing the patient does not have any of the following:
a. Significant pain with palpation of the plaque
b. Lack of full erectile response to prostaglandin E1 during curvature measurement
c. Isolated hourglass deformity
d. Ventral curvature
e. Calcified plaque
f. Plaque located proximal to the base of the penis
6. Documentation that the patient has been counseled on expectations of treatment (e.g., expected average curvature reduction is 17 degrees without reduction in pain or erectile dysfunction, potential for adverse effects)

Reauthorization after the initial two (2) treatment cycles (four (4) injections) will require documentation that

the curvature of the penis remains greater than 15 degrees

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For Dupuytren’s contracture: Authorization will be approved for three (3) months for a maximum of two (2) treatment courses.
For Peyronie’s disease: Initial authorization will be approved for three (3) months, not to exceed four (4) injections. Reauthorization will be approved for six (6) months, not to exceed eight (8) injections per lifetime.

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
Traveler's diarrhea (200 mg tablets):
1. 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):
1. 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):
1. Documentation of trial and failure, contraindication, or intolerance to TWO (2) of the following medications:
a. Anti-spasmodic agent [e.g. dicyclomine (Bentyl®)]
b. Tricyclic antidepressant [e.g. amitriptyline (Elavil®)]
c. Opioid mu receptor agonist [e.g., loperamide (Imodium®), diphenoxylate (Lomotil®)]

Reauthorization in IBS-D requires documentation of initial response to treatment with rifaximin and recurrence of IBS-D symptoms. Limited to three (3) total 14-day course treatments (initial treatment and two reauthorizations).

QUANTITY LIMIT:
200-mg and 550-mg tablets: three (3) tablets per day

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 three (3) months

Reauthorization: Will be approved for up to two additional 14 day treatment courses (total of three (3) treatment courses per lifetime)

Traveler’s diarrhea (200-mg tablets): One-time 3-day treatment course (Quantity of nine (9) tablets)

Hepatic Encephalopathy (550 mg tablets): Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

OTHER CRITERIA

N/A

XOLAIR - MEDICAL BENEFIT

MEDICATION(S)
XOLAIR

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

REQUIRED MEDICAL INFORMATION
For asthma, must meet all of the following criteria:
1. Diagnosis of moderate to severe persistent allergic asthma
2. IgE baseline levels greater than 30 IU/ml
3. Positive skin test to a common perennial aeroallergens
4. Documentation that in the past 3 months patient is adherent to a combination of a high-dose inhaled corticosteroids and a long-acting inhaled beta2-agonist. (This may be verified by pharmacy claims information)
5. Documentation of 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 2 exacerbations requiring oral systemic corticosteroids in the last 12 months
c. At least 1 exacerbation requiring hospitalization

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

For chronic idiopathic urticaria, must meet all of the following criteria:
1. Documentation that the condition is idiopathic and that secondary causes of urticaria (e.g. offending allergens, physical contact, etc.) have been ruled out
AND
2. Trial and failure of a second-generation non-sedating H1 antihistamine (e.g., levocetirizine, loratadine, cetirizine, fexofenadine)
AND
3. Trial and failure of one additional medication from the following classes: leukotriene receptor antagonists (e.g., montelukast), first generation H1 antihistamine (e.g., diphenhydramine), or histamine H2-receptor antagonist (e.g., famotidine, ranitidine)

Reauthorization for chronic idiopathic urticaria will require documentation of response to therapy (e.g. reduction in flares or oral steroid dose).

AGE RESTRICTION

Treatment of asthma: Approved for 6 years of age or older.
Treatment of urticaria: Approved for 12 years of age or older.

PRESCRIBER RESTRICTION

Urticaria: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist

Asthma: Must be prescribed by, or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist).

COVERAGE DURATION

Urticaria: Initial authorization will be for six months. Reauthorization will be for one year.
Asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA

N/A

XURIDEN

MEDICATION(S)
XURIDEN

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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/XYWAV

MEDICATION(S)
XYREM, XYWAV

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:
9 grams per day, which is 540 mL/30 days.

There is no evidence of additional benefit achieved with 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

ZINPLAVA - MEDICAL BENEFIT

MEDICATION(S)
ZINPLAVA

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with existing heart failure

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met for Clostridium difficile infection (CDI):
1. Previous trial of standard-of-care antibiotic regimen for recurrent CDI (e.g., oral vancomycin, fidaxomicin)
AND
2. Patient has at least one risk factor for higher likelihood of recurrent CDI (e.g. an age of 65 years or older, a history of C. difficile infection, compromised immunity, clinically severe C. difficile infection (defined as a Zar score greater than or equal to 2, scores range from 1 to 8, with higher scores indicating more severe infection))
AND
3. Zinplava® must be used in combination with standard-of-care antibiotics for treatment (e.g., oral vancomycin, fidaxomicin)

Reauthorization requires:
1. Previous dose was at least twelve (12) months prior
AND
2. Patient must have had documented benefit from previous infusion, defined as reduction in frequency of recurrences of CDI from baseline

AGE RESTRICTION
Approved for 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an infectious disease specialist or gastroenterology specialist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for a one-time intravenous dose at 10 mg/kg (subject to audit).

OTHER CRITERIA

N/A

ZOLGENSMA

MEDICATION(S)
ZOLGENSMA

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA
• Use in combination with Spinraza (nusinersen) therapy
• Repeat infusion of onasemnogene abeparvovec
• Advanced symptoms of SMA (e.g., complete paralysis of limbs, tracheostomy or ongoing invasive ventilator support in the absence of an acute reversible illness)

REQUIRED MEDICAL INFORMATION
1. Confirmed genetic diagnosis of SMA with documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and less than or equal to 3 copies of SMN2
2. Documentation that premedication with prednisolone 1 mg/kg/day (or equivalent) will be started 24 hours prior to infusion and continue for at least 30 days
3. Documentation of baseline anti-AAV9 antibody titers of less than or equal to 1:50
4. Documentation of baseline tests for liver function, platelet count, and troponin-I

AGE RESTRICTION
May be covered for patients 2 years of age and under

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

COVERAGE DURATION
Authorization will be approved for a one-time infusion

OTHER CRITERIA
N/A

ZYFLO CR

MEDICATION(S)
ZILEUTON ER, ZYFLO CR

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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
Approved for 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