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.
ACIPHEX SPRINKLE/DELIXANT/ESOMEPRAZOLE STRONTIUM CAPSULES/NEXIUM

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
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 up to one year

OTHER CRITERIA
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)
ACNE MEDICATIONS

MEDICATION(S)
ADAPALENE 0.1% GEL, ADAPALENE 0.3% GEL, AMNESTEEM, ATRALIN, AVITA 0.025% CREAM, BENZAACLIN GEL, BENZAMYCIN, PR BENZOYL PEROXIDE 7% WASH, BP WASH 7% LIQUID, CLARAVIS, CLEOCIN T 1% GEL, CLEOCIN T 1% PLEDGETS, CLEOCIN T 1% SOLUTION, CLINDACIN ETZ 1% PLEDGET, CLINDACIN P, CLINDAMAX 1% GEL, CLIND PH-BENZOYL PEROX 1.2-5%, CLINDAMYCIN PH 1% GEL, CLINDAMYCIN PH 1% SOLUTION, CLINDAMYCIN PHOS 1% PLEDGET, CLINDAMYCIN-BENZOYL PEROX 1-5%, DIFFERIN 0.1% GEL, DIFFERIN 0.3% GEL, DUAC, EFFACLAR ADAPALENE, EMCIN CLEAR, ERY, ERYTHROMYCIN 2% PLEDGETS, ERYTHROMYCIN 2% SOLUTION, ERYTHROMYCIN-BENZOYL PEROXIDE, ISOTRETINOIN 10 MG CAPSULE, ISOTRETINOIN 20 MG CAPSULE, ISOTRETINOIN 30 MG CAPSULE, ISOTRETINOIN 40 MG CAPSULE, KLARON, MYORISAN, NEUAC GEL, PACNEX, 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
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
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
1. Documentation that patient has one 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
MEDICATION(S)
ADAKVEO

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

EXCLUSION CRITERIA
Used in combination with voxelotor

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 6 months
   b. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least 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
**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 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 ages 18 years and older.

**PRESCRIBER RESTRICTION**
N/A

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

**OTHER CRITERIA**
1. Patient is female and pre-menopausal
   AND
2. Diagnosis of one of the following:
   a. Acquired, generalized hypoactive sexual desire disorder (HSDD)
   OR
   b. Female sexual interest/ arousal disorder
   AND
3. Patient has no known history of alcohol abuse
   AND
4. Patient will abstain from alcohol use during treatment
Reauthorization requires documentation that the patient continues to be pre-menopausal, continues to abstain from alcohol, and has responded to the medication.
AEMCOLO

MEDICATION(S)
AEMCOLO

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
Medicaid Only: 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
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 a 3-day treatment course.

OTHER CRITERIA
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
MEDICATION(S)
ALBENDAZOLE 200 MG TABLET, ALBENZA, EMVERM, MEBENDAZOLE 100 MG TAB CHEW, VERMOX

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit and pinworm (Enterobius vermicularis), which is an off-label use for Albenza®.

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
See “Other Criteria”

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

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

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

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
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.

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

For diarrhea caused by Giardia:
1. Confirmed diagnosis of Giardia
   AND
2. Documentation of trial and failure, intolerance, or contraindication to tinidazole
QUANTITY LIMIT:
Nitazoxanide (Alinia®) 500 mg tablets: 6 tablets per day 30 days
Nitazoxanide (Alinia®) 100 mg/ 5 ml suspension: 150 ml per 30 days
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
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
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 initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

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

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

Note: itraconazole capsules are not covered for this indication. Their use is not supported by Infectious Diseases Society of America (IDSA) guidelines, as they were considered less effective than fluconazole.

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

3. For the treatment of blastomycosis or histoplasmosis: itraconazole may be covered
   a. For voriconazole: Documented failure, intolerance, or contraindication to itraconazole
   Note: posaconazole is not covered for this indication

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

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

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

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

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

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

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

EXCLUSION CRITERIA
Use for prophylaxis against malaria

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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

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

For the prevention of toxoplasmosis (pyrimethamine only):
1. Documentation that the patient has HIV with a CD4 count less than 100 cells/uL
AND

2. Documented intolerance or contraindication to prophylaxis with trimethoprim-sulfamethoxazole

For reauthorization: documentation that the patient's CD4 count remains below 200 cells/μL
MEDICATION(S)
APOKYN

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
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 one year

OTHER CRITERIA
1. Patient has advanced Parkinson’s disease and is experiencing acute intermittent hypomobility (“off” episodes) lasting at least 2 hours
   AND
2. Patient is on other medications for the treatment of Parkinson’s disease (e.g., carbidopa/levodopa, pramipexole, ropinirole, benztropine, etc.)
MEDICATION(S)
ARANESP, EPOGEN, PROCRIT, RETACRIT

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

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

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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

ii. One of the following clinical scenarios:
   1. Patient has comorbid chronic kidney disease
   2. Patient undergoing palliative treatment
   3. Patient is currently on myelosuppressive chemotherapy and anemia is not able to be managed by transfusion therapy

c. Treatment of Anemia in Myelodysplastic Syndromes (MDS) or with myelofibrosis
   i. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level 100 mcg/L or serum transferrin saturation 20%
   ii. Must have documented current (within last 3 months) endogenous serum erythropoietin levels less than or equal to 500 mU/mL

d. Anemia associated with zidovudine-treated HIV-infection patients
   i. Documented current (within last 3 months) endogenous serum erythropoietin level is less than or equal to 500 mU/ml
   ii. Zidovudine dose is less than or equal to 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
MEDICATION(S)
ARIKAYCE

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 infectious disease specialist, or pulmonologist

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

OTHER CRITERIA
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. Documented trial, failure, intolerance or contraindication to intravenous aminoglycoside (streptomycin or amikacin) and inhaled amikacin sulfate
AND
4. Documentation that organism is susceptible to amikacin

Reauthorization requires documentation of negative sputum cultures.
QUANTITY LIMIT:
28 vials per month (8.4 ml/day)
BENLYSTA

MEDICATION(S)
BENLYSTA

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

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

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

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

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

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

OTHER CRITERIA
All of the following must be met:
1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) by a rheumatologist
   AND
2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one (1) of the following:
   a. Positive Antinuclear antibody (ANA)
   b. Positive anti-double-stranded DNA (anti-dsDNA) on two (2) or more occasions, OR if tested by ELISA, an
antibody level above laboratory reference range
c. Positive anti-Smith (Anti-Sm)
d. Positive anti-Ro/SSA and anti-La/SSB antibodies

AND

3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one (1) of the following:
   a. Oral corticosteroid(s)
   b. Azathioprine
   c. Methotrexate
d. Mycophenolate mofetil
e. Hydroxychloroquine
   f. Chloroquine
g. Cyclophosphamide

4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, hydroxychloroquine, mycophenolate, azathioprine, methotrexate)

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

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

MEDICATION(S)
JEUVEAU

COVERED USES
All Food and Drug Administration (FDA) approved and selected medically accepted indications not otherwise excluded from the benefit, as outlined below.

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
• 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
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
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. Antiepileptics (e.g., divalproex, valproate, topiramate)
c. Documentation that onabotulinumtoxinA will not be used in combination with Calcitonin Gene-Related Peptide (CGRP) Inhibitors (e.g., Aimovig®)

2. Upper and lower limb spasticity in adults
3. Upper limb spasticity in pediatric patients at least 2 years of age
4. Lower limb spasticity in pediatric patients at least 2 years of age that is not due to cerebral palsy
5. Cervical dystonia in adults
6. Strabismus and blepharospasm associated with dystonia in patients at least 12 years of age
7. 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.
8. 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)
9. 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)
10. Excessive salivation due to advanced Parkinson’s disease
11. Hemifacial spasm

AbobotulinumtoxinA (Dysport®) may be covered for the following indications:
1. Spasticity in adults
2. Cervical dystonia in adults
3. Lower-limb spasticity in patients at least 2 years of age
4. Upper limb spasticity in pediatric patients at least 2 years of age that is not due to cerebral palsy.
5. Blepharospasm in adults

IncobotulinumtoxinA (Xeomin®) may be covered for the following indications:
1. Chronic sialorrhea in adult patients
2. Upper limb spasticity in adult patients
3. Cervical dystonia in adults
4. Blepharospasm in adults

RimabotulinumtoxinB (Myobloc®) may be covered for the following indications:
1. Cervical dystonia in adults
2. Chronic sialorrhea in adult patients
BPH TREATMENT- CIALIS, RAPAFL0

MEDICATION(S)
CIALIS 5 MG TABLET, RAPAFL0, SILODOSIN, TADALAFIL 5 MG TABLET

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

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

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

For Medicaid Only:
For tadalfil (Cialis®) 5 mg daily for signs and symptoms of benign prostatic hyperplasia (BPH):
Documentation of an adequate trial and failure*, intolerance, or contraindication to at least one formulary drug from EACH of the categories listed below:
1. Alpha-adrenergic blockers (e.g. tamsulosin, doxazosin, terazosin, alfuzosin)
AND
2. 5-alpha reductase inhibitor (e.g. finasteride or dutasteride)
*An adequate trial and failure is defined as daily use for at least 4 weeks of therapy without improvement in signs and symptoms of BPH.

QUANTITY LIMIT:
Cialis® (tadalafil) 5 mg: 30 tablets per 30 days for BPH
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 ß-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.
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 initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For Propuphine®: 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.
For Sublocade®: Initial authorization and reauthorization will be approved for 6 months.

OTHER CRITERIA
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
CABLIVI

MEDICATION(S)
CABLIVI

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 patients 18 years of age and older

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

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

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

Reauthorization criteria:
If the request is for a new treatment cycle:
1. Documentation of previous positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers)
2. Documentation that therapy will be given in combination with plasma exchange therapy and immunosuppressive therapy (i.e., glucocorticoids, rituximab)
3. Documentation that length of therapy post plasma exchange will not exceed 58 days
4. Documentation that patient has not had more than two recurrences of acquired thrombotic thrombocytopenic purpura while on therapy with caplacizumab. Recurrence is defined as initial platelet normalization followed by a reduction in platelet count that necessitates re-initiation of plasma exchange. If request is for treatment extension:

1. Documentation of positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers)

2. Documentation that patient has signs of persistent underlying disease such as persistent severe ADAMTS13 deficiency

3. Documentation that length of therapy post plasma exchange will not exceed 58 days

QUANTITY LIMIT:

1 vial per day
CALCITONIN GENE-RELATED PEPTIDE (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
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.

QUANTITY LIMIT:
9 packets per 30 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A
CAR-T (KYMRIAH, YESCARTA) - MEDICAL BENEFIT

MEDICATION(S)
KYMRIAH, YESCARTA

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

EXCLUSION CRITERIA
• Previous treatment with chimeric antigen receptor therapy or other genetically modified T-cell therapy
  o Repeat administration of CAR-T therapy is considered experimental and investigational because the effectiveness of this approach has not been established
• History of allogenic stem cell transplantation and primary central nervous system (CNS) lymphoma
• Presence of history of CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, brain metastases, or any autoimmune disease with CNS involvement
• 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
Kymriah:
• 25 years of age or younger for acute lymphoblastic leukemia (ALL)
• 18 years of age and older for relapsed or refractory large B-cell lymphoma
Yescarta:
• 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:
• 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), Kymriah 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, Yescarta or Kymriah 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
MEDICATION(S)
KALYDECO, ORKAMBI, SYMDEKO, TRIKAFTA

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

EXCLUSION CRITERIA
N/A

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

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

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

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

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

QUANTITY LIMIT:
Ivacaftor (Kalydeco®): 2 tablets/granule packets per day
Lumacaftor-ivacaftor (Orkambi®): 4 tablets per day
Tezacaftor-ivacaftor (Symdeko™): 2 tablets per day
Elexacaftor- tezacaftor-ivacaftor (Trikafta™): 3 tablets per day

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

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

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

**OTHER CRITERIA**
N/A
MEDICATION(S)
CHENODAL

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 is necessary.

AGE RESTRICTION
N/A

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

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

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

OTHER CRITERIA
For use in gallstone dissolution:

1. Documentation that the patient is not a candidate for surgery
AND
2. Documentation of failure of an adequate trial of 6-month duration, contraindication, or intolerance to ursodiol

Reauthorization: Documentation of positive clinical response to therapy
MEDICATION(S)
CHOLBAM

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. Patient weight. Dose and frequency requested. Baseline liver function tests (AST, ALT, GGT, ALP, total bilirubin, INR)

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
For bile acid synthesis disorder: documentation of a single enzyme defect

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

Reauthorization: Documentation of positive clinical response
MEDICATION(S)
CINRYZE, HAEGARDA, TAKHZYRO

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

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

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
All of the following must be met:
1. Documentation of one of the following clinical criteria:
   a. Self-limiting, noninflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours, or
   b. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six hours, or
   c. Recurrent laryngeal edema
   AND
2. Documentation of greater than or equal to 2 HAE attacks per month on average for the past 3 months despite removal of triggers (eg. estrogen containing oral contraceptive, angiotensin converting enzyme inhibitors) unless medically necessary
3. Trial and failure, intolerance or contraindication to long-term prophylaxis with androgen therapy, such as danazol, stanozolol or oxandrolone unless not indicated (eg. pregnancy, lactation, pre-pubescent children),

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

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

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

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

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

MEDICATION(S)
AMITIZA, LINZESS, MOTEGRITY, MOVANTIK, SYMPROIC, TRULANCE

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

For Medicaid: Constipation is considered “below the line.” Therefore, coverage is dependent on whether the constipation adversely affects, or is secondary 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. The following conditions are not covered:
• Chronic idiopathic constipation
• Constipation secondary to irritable bowel syndrome
• Opioid-induced constipation in patients with non-cancer pain

EXCLUSION CRITERIA
Current, or history of, bowel obstruction

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 6 months. Reauthorization will be approved for one year

OTHER CRITERIA
1. For all requests, the patient must have an FDA labeled indication for the requested agent.
2. For patients already established on the requested product (starting on samples will not be considered as established on therapy):
   a. Documentation of response to therapy (e.g., less straining, less pain on defecation, improved stool consistency, increased number of stools per week or reduction in the number of days between stools)
3. For patients not established on the requested product must meet ALL of the following indication-specific
criteria:
a. For chronic idiopathic constipation (CIC):
i. Documentation of weekly constipation (less than 3 spontaneous bowel movements) for at least 3 months
ii. Screen for constipation-inducing medications and medical rationale provided for continuing these medications, if applicable
iii. Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of ALL of the following:
   (1) Regular use of dietary fiber supplementation (e.g. cereal, citrus, fruits or legumes) or use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids),
   (2) A stimulant laxative (e.g. senna, bisacodyl)
   (3) Routine laxative therapy, with a different mechanism of action than the laxative(s) listed above (e.g., lactulose, Miralax®)
b. For irritable bowel syndrome with constipation (IBS-C):
i. Documentation of recurrent abdominal pain occurring, on average, at least 1 day per week during the previous 3 months with two (2) or more of the following criteria:
   (1) Related to defecation (either increased or improved pain)
   (2) Associated with a change in stool frequency
   (3) Associated with a change in stool form (appearance)
ii. Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of ALL of the following:
   (1) Regular use of dietary fiber supplementation (e.g. cereal, citrus, fruits or legumes) or use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids)
   (2) Routine laxative therapy with polyethylene glycol (Miralax®)
iii. For Amitiza®: patient is a woman aged 18 years or older
iv. For Zelnorm®: patient is a woman aged 65 years or younger without contraindication to therapy.
Contraindications include:
(1) History of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina
(2) History of ischemic colitis or other forms of intestinal ischemia, bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi dysfunction, or abdominal adhesion
(3) Moderate or severe hepatic impairment
(4) Severe renal disease or end-stage renal disease
c. **For opioid-induced constipation (OIC) (Amitiza®, Movantik®, and Symproic® only):
i. Documentation of less than 3 spontaneous bowel movements per week
ii. Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of ALL of the following:
   (1) A stimulant laxative (e.g. senna, bisacodyl)
   (2) Routine laxative therapy, with a different mechanism of action than the laxative above (e.g. lactulose, Miralax®)

**For Medicaid, please note that chronic constipation secondary to continuous opioid use as part of a
palliative care regimen, or for treatment of active cancer pain, is approvable without meeting criterion c.ii. only if medical rationale is sufficient
**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 initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

**AGE RESTRICTION**
N/A

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

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

**OTHER CRITERIA**
For chronic heart failure, all of the following must be met:
1. Symptoms consistent with New York Heart Association (NYHA) Class II, III, or IV
2. Left ventricular ejection fraction (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
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. Diagnosis of X-linked hypophosphatemia (XLH) supported by ONE or more of the following:
   a. Confirmed PHEX mutation in the patient or a directly related family member with appropriate X-linked inheritance
   b. Elevated Serum fibroblast growth factor 23 (FGF23) level greater than 30 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
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
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
All Food and Drug Administration (FDA)-approved indications not otherwise excluded in the benefit.

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

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

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

QUANTITY LIMIT:
Acyclovir buccal tablets (Sitavig®) is limited to one 50mg tablet per 30 days.
**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 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 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 and reauthorization will be approved for 1 year.

**OTHER CRITERIA**
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 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
DIHYDROERGOTAMINE

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

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

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
MEDICATION(S)
OMNIPOD DASH 5 PACK POD

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

Oregon: Services requested for Medicaid members follow the Oregon Health Authority (OHA) Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the Prioritized List.

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

OTHER CRITERIA
1. For initial authorization patients must meet one of the following:
   a. Patient has Type 1 diabetes
   b. Patient has Type 2 diabetes and meets all of the following criteria:
      i. The patient has completed a comprehensive diabetes education program
      ii. The patient has been on a program of multiple daily injections of insulin (i.e., at least 2 injections per day)
      iii. The patient has either a documented ability to self-adjust insulin dose for at least 6 months prior to initiation of the insulin pump, or has a documented ability to successfully use a continuous glucose monitor
      iv. The patient has a documented ability to glucose self-test at least four times daily while on insulin
v. The patient meets at least one of the following criteria while on the multiple injection regimen:
1. Glycosylated hemoglobin level (HbA1C) greater than 7%
2. History of recurring, symptomatic hypoglycemia
3. Fasting blood sugars frequently exceeding 200 mg/dL
4. History of severe glycemic fluctuations
5. Documented need for more than 5 daily injections of insulin

QUANTITY LIMIT:
Omnipod Dash pods: 10 pods per 30 days
DOPTELET, MULPLETA

MEDICATION(S)
DOPTELET, MULPLETA

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

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Approved for 18 years of age and older.

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

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

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

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

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

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

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

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

QUANTITY LIMIT:
For Mulpleta®: 7 tablets per month
DPP4 INHIBITORS

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

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

EXCLUSION CRITERIA
Type 1 diabetes

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

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
Initial authorization and reauthorization for 12 months.

OTHER CRITERIA
N/A
DRONABINOL

MEDICATION(S)
DRONABINOL, MARINOL

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

OTHER CRITERIA
For nausea and vomiting associated with cancer chemotherapy:
1. Patient must meet the following criteria:
   a. Documentation of trial and failure, contraindication or intolerance to a 5HT-3 receptor antagonist (e.g., ondansetron).
   AND
   b. Documentation of trial and failure, contraindication or intolerance to one of the following formulary medications unless contraindicated: promethazine, prochlorperazine, chlorpromazine, or metoclopramide.

For anorexia with weight loss in patients with AIDS:
1. Documentation that patient is currently taking anti-retroviral therapy
2. If patient is less than 65 years of age: Documentation of trial and failure, contraindication, or intolerance
to megestrol (Megace®)
MEDICATION(S)
DUPIXENT SYRINGE

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

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.

Eosinophilic and corticosteroid dependent asthma: Absolute Eosinophil Count, and Asthma Control Test (ACT) or Asthma Control Questionnaire (ACQ) score

AGE RESTRICTION
• Moderate-to-severe atopic dermatitis: Age 12 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
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA
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, azathioptine, 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 β2-agonist and has been compliant to therapy in the past 3 months (this may be verified by pharmacy claims information)

3. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following:
   a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than 1.5
   b. At least 2 asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
   c. At least 1 asthma exacerbation requiring hospitalization, emergency room or urgent care visit

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

For corticosteroid dependent asthma:
1. Documentation of corticosteroid dependent asthma defined as consistent treatment with oral corticosteroids for the past six months (5 mg to 35 mg of prednisone/prednisolone (or equivalent)). (This may be verified by pharmacy claims information).

2. Documentation that in the past 3 months patient is adherent to a combination of a high-dose inhaled corticosteroid and a long-acting inhaled beta2-agonist. (This may be verified by pharmacy claims information)

3. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following:
   a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than 1.5
   b. Documentation, within the last 12 months, of one or more asthma exacerbations defined as any of the following:
      i. Increase in dose of systemic corticosteroid treatment
      ii. Urgent care visit or hospital admission
      iii. Intubation

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

Adjunct Therapy for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), all of the following must be met:
1. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan
2. Documentation of one (1) of the following:
   a. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery
   b. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids
3. Patient has tried and had an inadequate response to a 3-month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids
4. Documentation that patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with dupilumab

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

QUANTITY LIMIT:
Two (2) 200 mg injections per 28 days
Two (2) 300 mg injections per 28 days.

Note:
• The recommended dose of Dupixent® for adults with atopic dermatitis is an initial loading dose of 600 mg (two 300 mg injections) subcutaneously, followed by 300 mg given every other week for maintenance.
• The recommended dose of Dupixent® for adolescents (12 year of age and older) for eosinophilic and oral corticosteroid dependent asthma is an initial loading dose of 400 mg (two 200 mg injections) or 600 mg (two 300 mg injections) subcutaneously, followed by 200 mg or 300 mg given every other week for maintenance.
• The recommended dose of Dupixent® for adults with CRSwNP is 300 mg every other week.
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, PIMECROLINE, PROTOPIC, TACROLIMUS 0.03% OINTMENT, TACROLIMUS 0.1% OINTMENT

COVERED USES
Psoriasis, oral lichen planus and all Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

Note: 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

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 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 for 3 months. Reauthorization for 12 months.

OTHER CRITERIA
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 (2 weeks or longer) of two 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).

AND

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

MEDICATION(S)
ELZONRIS

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 oncologist or hematologist

COVERAGE DURATION
Initial and reauthorization will be approved for 6 months

OTHER CRITERIA
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
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.
MEDICATION(S)
CALCIPOTRIENE-BETAMETHASONE, CALCIPOTRIENE-BETAMETHASONE DP, ENSTILAR, TACLONEX

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

AGE RESTRICTION
12 years of age and older

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
For treatment of psoriasis on the scalp, documentation of trial, failure, contraindication or intolerance to both of the following:
1. Corticosteroid treatment for the scalp (e.g., clobetasol shampoo, fluocinolone scalp oil/solution)
2. Calcipotriene solution
For treatment of psoriasis of the body:
1. Documentation of trial, failure, contraindication or intolerance to at least one high-potency corticosteroid treatment (e.g., clobetasol, betamethasone)
2. Documentation of trial, failure, contraindication or intolerance to at least one of the following:
a. Calcipotriene cream/solution
b. Tazarotene cream or gel

c. Calcitriol ointment
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® (algalsidase 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.
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
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 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
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)
2. Documented trial, failure, intolerance or contraindication to clobazam
3. Documented trial, failure, intolerance or contraindication to one additional of the following:
   a. Valproate / Valproic acid
   b. Lamotrigine
   c. Levetiracetam
   d. Topiramate
   e. Felbamate
   f. Zonisamide
4. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs
5. Baseline liver function tests must be documented
6. Dose will not exceed 20 mg/kg/day

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
**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
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 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 age 2 years and older.

PRESCRIBER RESTRICTION
N/A

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

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

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 six months

OTHER CRITERIA
All of the following criteria must be met:
1. One of the following:
a) Patient has a substance use disorder, is at risk of overdose with heroin or opioids and a discussion between the provider and patient has occurred regarding substance abuse treatment plans
OR
b) Patient is receiving opioid therapy totaling more than 50 morphine equivalents per day (MED), which may be verified by pharmacy claims, and the patient is at high risk for opioid overdose, as defined by one of the following risk factors:
   i) History of opioid overdose
   ii) History of, or current, substance abuse (e.g., heroin)
   iii) Concomitant use with benzodiazepines, antidepressants, alcohol, or muscle relaxants
   iv) Chronic pulmonary disease (e.g. emphysema, chronic bronchitis, asthma)
   v) Sleep apnea
   vi) Illness that may affect metabolism of opioids (e.g., renal impairment, chronic cirrhosis or hepatitis)
vii) Mental illness (e.g. bipolar disorder, schizophrenia)
viii) Cognitive impairment

2. Medical justification supported by chart note documenting why the patient’s caregiver is unable to use:
   a) 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
   b) Narcan® nasal spray
   AND
   c) For brand Evzio® only: generic naloxone auto-injector

For Reauthorization
   1. Product reached expiration date without use
   OR
   2. If product was used for overdose: Documentation of a reduction in total MED (for chronic pain patients) or planned substance abuse treatment (for heroin/opioid abusers)

QUANTITY LIMIT:
2 doses per year
EXON-SKIPPING THERAPIES FOR DUCHENNE MUSCULAR DYSTROPHY

**MEDICATION(S)**
EXONDYS-51, 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) and golodirsen (Vyondys® 53) are not considered medically necessary and will not be covered, at this time, due to the lack of clinical evidence of improved outcomes and safety.
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
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 one year.

OTHER CRITERIA
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 (Gilenyana®)
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
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
Repetitive Nerve Stimulation (RNS) or anti-P/Q type voltage-gated calcium channel antibody test.

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 approval will be approved for 3 months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
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:
Documentation of improvement or stabilization of muscle weakness from baseline
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
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
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
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 10^9/L, neutrophils less than 1 x 10^9/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 greater than 1x10^9/L, platelets greater than 100x10^9/L, ferritin less than 2,000 µg/L, fibrinogen greater than 1.50g/L, D-dimer less than 500 µg/L, normal CNS symptoms, no worsening of sCD25 greater than 2-fold baseline)
   b. Partial response defined as normalization of ≥3 HLH abnormalities
   c. HLH improvement defined as ≥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
**GAMMA GLOBULIN (IGG)**

**MEDICATION(S)**
ASCENIV, BIVIGAM, CARIMUNE NF NANOFILTERED, CUTAQUIG, CUVITRU, FLEBOGAMMA DIF, GAMASTAN, GAMASTAN S-D, GAMMAGARD LIQUID, GAMMAGARD S-D 10 G (IGA<1) SOL, GAMMAGARD S-D 5 G (IGA<1) SOLN, GAMMAKED, GAMMAPLEX, GAMUNEX-C, HIZENTRA, HYQVIA, OCTAGAM, PANZYGA, PRIVIGEN, XEMBIFY

**COVERED USES**
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit. Off-label uses may be approved according to the clinical criteria outlined in the below policy.

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Patient weight, dose, frequency and duration

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

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

**AGE RESTRICTION**
N/A

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

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

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

Re-Authorization for ALL indications:
Documentation of response to therapy and any indication specific re-authorization criteria listed below is met

Indication-Specific Requirements:

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

Reauthorization:
Documentation that treatment has been effective in reducing the number or severity of clinical infections

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

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

Idiopathic or Immune Thrombocytopenic Purpura (ITP):
(Platelet counts expressed per mm3 and should be obtained within the past 30 days)
For children with ITP:
1. Documentation of one of the following:
a. Platelet count less than 20,000 and significant mucous membrane bleeding
b. Platelet count less than 10,000 and minor purpura
c. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss

Pregnant Women with ITP:
1. Documentation of one of the following:
a. Platelet count is less 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. Therapy is requested for use within 100 days after transplantation (documentation of transplantation date much be documented)
OR
2. Documentation of that member has hypogammaglobulinemia (see criteria for Secondary Hypogammaglobulinemia)

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

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 1 year and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a Gastroenterologist

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

OTHER CRITERIA
1. An initial nutritional assessment has been completed by a registered dietitian who has determined that oral/enteral nutrition is not sufficient to meet nutritional goals
2. Member is stable and dependent on parenteral support (fluids, electrolytes and/or nutrients) delivered at least three times per week
3. Teduglutide (Gattex®) has been made part of a treatment plan established by a Gastroenterologist or a hospital Metabolic Support Team:
   a. Member evaluation indicates the possibility of success with treatment
   b. Parameters have been defined to identify goals and measure improvement

Reauthorization: Documentation that parenteral nutrition support requirement has decreased since initiation of teduglutide

QUANTITY LIMITS:
Round quantity to the nearest number of 5-mg kits, within 10% of calculated dose, based on weight-based
dosing of 0.05 mg/kg once daily
**MEDICATION(S)**
GIVLAARI

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

**EXCLUSION CRITERIA**
Use post liver transplant

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

**AGE RESTRICTION**
N/A

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

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

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

Reauthorization criteria: documentation of reduction in the number or severity of porphyria attacks, reduction in number of hospitalizations due to acute porphyria attacks, or decreased hemin administration from baseline
GNRH ANTAGONISTS

MEDICATION(S)
ORILISSA

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

EXCLUSION CRITERIA
• Patient has osteoporosis or severe hepatic impairment

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

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

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

COVERAGE DURATION
Orilissa® 150 mg once daily: Initial authorization for 6 months. Reauthorization for up to 18 months. No reauthorization beyond 24 months
Orilissa® 200 mg twice daily: Initial authorization for 6 months. No reauthorization.

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

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

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

**COVERED USES**
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit. Medically necessary off-label uses may be approved according to the clinical criteria outlined in the policy.

**EXCLUSION CRITERIA**
Treatment of male infertility

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

**OTHER CRITERIA**
For oncological indications: Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
For anemia associated with uterine leiomyomata (fibroids)
1. Documented trial, failure, intolerance or contraindication to at least 30 days of therapy with iron supplementation alone
AND
2. Documentation that Lupron® will be used in combination with iron supplementation

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

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

Reauthorization for Lupron® requires documentation that it will be used in combination with “add-back” progesterone therapy (e.g. norethindrone) to help prevent bone mineral density loss.
Reauthorization for Synarel® and Zoladex® is not recommended. Treatment is only recommended for up to 6 months with these agents for endometriosis

For central precocious puberty
Note, a one-time dose may be approved for diagnostic purposes

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

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

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

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

For Endometrial thinning/dysfunctional uterine bleeding:
1. Documentation for use prior to endometrial ablation
MEDICATION(S)
HEMLIBRA

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 reauthorization will require a current weight (within the past 6 months). 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
To be prescribed by, or in consultation with a hematologist.

COVERAGE DURATION
Initial authorization: 6 months
Reauthorization: 12 months

OTHER CRITERIA
1. Use is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
2. Diagnosis of hemophilia A (congenital factor VIII deficiency) and documentation of ANY of the following:
   a. Factor VIII inhibitors (defined as ? 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 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)
HEPATITIS C- DIRECT ACTING ANTIVIRALS

MEDICATION(S)
DAKLINZA, EPCLUSA, HARVONI 45-200 MG TABLET, HARVONI 90-400 MG TABLET, LEDIPASVIR-SOFOSBUVIR, MAVYRET, OLYSIO, SOFOSBUVIR-VELPATASVIR, SOVALDI 200 MG TABLET, SOVALDI 400 MG TABLET, TECHNIVIE, VIEKIRA PAK, VOSEVI, ZEPATIER

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

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
For initiation of treatment, a prior authorization form and relevant chart notes documenting specific HCV genotype, liver fibrosis score, Child-Pugh score if patient has cirrhosis, baseline HCV RNA count, NS5A polymorphisms status if applicable, complete blood count, liver panel, and renal function status are required.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Coverage duration will be based on genotype and regimen.

OTHER CRITERIA
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 year AND
3. Documentation that ALL of the following pre-treatment testing has been performed:
   a. Genotype testing in past 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. Pregnancy test in past 30 days for a woman of child-bearing age
Note: Currently treatment is not recommended during pregnancy due to lack of safety and efficacy data

d. 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.

e. Cirrhosis status as clinically determined (e.g., clinical, laboratory, or radiologic evidence)

AND

4. Documentation 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. (See Appendix 1 for detail)

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
HEREDITARY ANGIOEDEMA

MEDICATION(S)
BERINERT, FIRAZYR, ICATIBANT, KALBITOR, RUCONEST

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

EXCLUSION CRITERIA
N/A

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

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

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

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

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

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

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

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

QUANTITY LIMIT (subject to audit):
Berinert® - 2 injections per 30 days
Ruconest® - 2 injections per 30 days
Kalbitor® - 2 boxes (6 vials) per 30 days
Firazyr® - 3 injections (3 boxes, total of 9ml) per 30 days
MEDICATION(S)
HETLIOZ

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

EXCLUSION CRITERIA
Sleep disorders other than Non-24.

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 sleep specialist.

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

OTHER CRITERIA
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 and failure of at least one non-pharmacologic treatment for Non-24 (i.e. planned sleep schedules, timed light exposure)
6. Documented trial, failure, intolerance or contraindication to an adequate trial (at least 30 days) of melatonin
Reauthorization criteria:
1. Documentation of improvement in social, occupational, and other important areas of functioning AND
2. Documentation of entrainment to the 24-hour circadian period.

QUANTITY LIMIT:
Limited to 30 capsules per 30 days
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

REQURED 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 up to one year.

OTHER CRITERIA
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 one tricyclic antidepressant (TCA).

QUANTITY LIMIT:
30 tablets per 30 days
Quantities of 60 tablets per 30 days will be approved for postherpetic neuralgia
MEDICATION(S)
ACTHAR, H.P. 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.
MEDICATION(S)
GENOTROPIN, HUMATROPE, NORDITROPIN, NORDITROPIN FLEXPRO, NORDITROPIN NORDIFLEX,
NUTROPIN, NUTROPIN AQ, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SAIZEN-SAIZenPREP,
SEROSTIM, TEV-TROPIN, 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 meet 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
MEDICATION(S)
CINQAIR, FASENRA, FASENRA PEN, NUCALA

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 initial authorization, must meet all of the following criteria:
For eosinophilic asthma:
1. Documentation of eosinophilic asthma by one of the following:
   a. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months
   b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids
2. Documentation of treatment with maximally tolerated dose of medium to high-dose inhaled corticosteroid plus a long-acting inhaled beta 2-agonist and has been compliant to therapy in the past 3 months (this may be verified by pharmacy claims information)
3. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following:
   a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5
   b. At least two (2) asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
   c. At least one (1) asthma exacerbation requiring hospitalization, emergency room or urgent care visit

For Eosinophilic Granulomatosis with Polyangiitis (EGPA):
1. Request is for Nucala®
2. History or presence of asthma
3. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter
4. At least two of the following clinical findings:
   a. Biopsy evidence of eosinophilic vasculitis
   b. Motor deficit or nerve conduction abnormality
   c. Pulmonary infiltrates
   d. Sinonasal abnormality
   e. Cardiomyopathy
   f. Glomerulonephritis
   g. Alveolar hemorrhage
h. Palpable purpura
i. Positive test for ANCA

5. Documentation of one of the following
   a. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous 2 years while receiving at least 7.5 mg/day prednisone (or equivalent)
   OR
   b. Failure to achieve remission following a standard induction regimen administered for at least 3 months OR recurrence of symptoms of EGPA while tapering of glucocorticoids

i. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil

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

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

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

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

For Eosinophilic Granulomatosis with Polyangiitis: must be prescribed by or in consultation with a pulmonologist, neurologist, or rheumatologist

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

OTHER CRITERIA
N/A
INCRELEX

MEDICATION(S)
INCRELEX

COVERED USES
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, PROCHIEVE

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
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
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
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
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, BENEKA, BESPONSA, BLINCYTO, BORTEZOMIB, CYRAMZA, DACOGEN, DARZALEX, DECITABINE, EMPLICITI, ENHERTU, ERBITUX, FASLODEX, FOLOTYN, FULVESTRANT, HALAVENT, HERCEPTIN, HERCEPTIN HYLECTA, HERZUMA, IMFINZI, IMLYGIC, ISTODAX, IXEMPRER, JEVTANA, KADCYLA, KANJINTI, KEYTRUDA, KYPROLIS, LARTRUVO, LIBTAYO, LUMOXITI, LUTATHERA, MELPHALAN HCL, MVASI, OGIVRI, ONIVYDE, ONTRUZANT, OPDIVO, PADCEV, PERJETA, POLIVY, PORTRAZZA, POTOELIGEO, ROMIDEPSIN, SARCLISA, SYLATRON, SYLATRON 4-PACK, SYNRIBO, TECENTRIQ, TEMODAR 100 MG VIAL, TEMSIROLIMUS, TORISEL, TRAZIMERA, TREANDA, VECTIBIX, VELCADE, VIDAZA, VYXEOS, XOFIGO, YERVOY, YONDELIS, ZALTRAP, ZIRABEV

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

For off-label use criteria, please see the Chemotherapy Treatment Utilization Criteria: Coverage for Non-FDA Approved Indications ORPTCOPS105.

For bevacizumab given via intravitreal injection: See payment policy 97.0 Compound Drugs Administered in the Physician's Office

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

For initial authorization:
1. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
2. For Herceptin Hylecta® (trastuzumab and hyaluronidase-oysk): Documentation of trial and failure, intolerance, or contraindication to trastuzumab

For reauthorization: documentation of adequate response to the medication must be provided.
INTERLEUKIN – 1 INHIBITORS - ARCALYST, ILARIS

MEDICATION(S)
ARCALYST, ILARIS

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
Arcalyst® is approved for adults and children 12 years and older.
Ilaris® is approved for 4 years of age and older in patients with CAPS (which includes FCAS, MWS):
Periodic Fever Syndromes including TRAPS, HIDS/MKD, and FMF
Ilaris® is approved for 2 years of age and older in patients with Active Systemic Juvenile Idiopathic Arthritis

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
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 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 Systemic Juvenile Idiopathic Arthritis (SJIA):
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)
MEDICATION(S)
JUXTAPID, KYNAMRO

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
LDL level or genetic confirmation of Homozygous Familial Hypercholesterolemia

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
All of the following must be met:
1. Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) as evidenced by:
   a. Genetic confirmation OR
   b. Untreated LDL-C greater than 500 mg/dl and xanthoma OR
   c. Both parents are heterozygous FH
   AND

2. One of the following:
   a. Intolerable muscle side effects or biomarker changes (such as elevations of creatinine kinase) to at least two statins that decrease or resolve after discontinuation of therapy with statin.
   AND

3. An adequate trial and failure (3 months of therapy), contraindication or intolerance to the use of ezetimibe (Zetia®)
AND
4. An adequate trial and failure (3 months of therapy), contraindication or intolerance to the use of a formulary PCSK-9 inhibitor

Reauthorization must show documentation that LDL-C has decreased from pre-treatment levels.
KETOCONAZOLE (NIZORAL TABLETS)

MEDICATION(S)
KETOCONAZOLE 200 MG TABLET

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

EXCLUSION CRITERIA
Candida, tinea versicolor, or dermatophyte infections

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
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
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)

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

AGE RESTRICTION
Approved in 17 years and older

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A
KEVEYSIS

MEDICATION(S)
KEVEYSIS

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
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
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.
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
MEDICATION(S)
KRUSTEXX

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 Rheumatologist

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

OTHER CRITERIA
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
KUVAN

MEDICATION(S)
KUVAN

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
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
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 2 years or beyond 2 treatment courses.

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by a Neurologist who has been certified through the Lemtrada® REMS program.

COVERAGE DURATION
Initial authorization will be approved for one year. Reauthorization will be approved for one year. No authorization may be approved for treatment beyond 2 years.

OTHER CRITERIA
1. Documentation of confirmed diagnosis of relapsing form of multiple sclerosis
   AND
2. Documentation of active disease (e.g. patients with frequent attacks or who are rapidly progressing in disability) after an adequate trial to at least two of the following disease modifying therapies unless all are contraindicated.
   a. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®)
   b. Interferon-beta 1b (Betaseron®)
   c. Dimethyl fumarate (Tecfidera®)
   d. Glatiramer acetate (Copaxone®)
   e. Natalizumab (Tysabri®)
   f. Teriflunomide (Aubagio®)
   g. Fingolimod (Gilenya®)
h. Ocrelizumab (Ocrevus®)

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.
MEDICATION(S)
LIDOCAINE 5% PATCH, LIDODERM

COVERED USES
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit, diabetic peripheral neuropathy and cancer-related neuropathic pain

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 for 3 months. Reauthorization for 6 months.

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

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

Reauthorization will require documentation submitted showing adequate response to therapy.
LONG ACTING OPIOIDS

MEDICATION(S)
ARYMO ER, AVINZA, BELBUCA, BUPRENORPHINE, BUTTRANS, EMBEDA, EXALGO, HYDROCODONE BITARTRATE ER, HYDROMORPHONE ER, HYSINGLA ER, KADIAN ER 10 MG CAPSULE, KADIAN ER 100 MG CAPSULE, KADIAN ER 20 MG CAPSULE, KADIAN ER 200 MG CAPSULE, KADIAN ER 30 MG CAPSULE, KADIAN ER 40 MG CAPSULE, KADIAN ER 50 MG CAPSULE, KADIAN ER 60 MG CAPSULE, KADIAN ER 80 MG CAPSULE, 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
MEDICATION(S)
LUXTURNA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Results of RPE65 gene test

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 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
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 greater than 100 micrometer thickness shown on optical coherence tomography: and
   b. The member has remaining light perception in the intended treatment eye
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
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 age 18 years of age 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 year. Treatment beyond 2 years will not be authorized

OTHER CRITERIA
Documented trial and failure, intolerance, or contraindication to two (2) conventional therapies for multiple sclerosis.
MEDICAID INTRANASAL ALLERGY MEDICATIONS

MEDICATION(S)
24 HOUR NASAL ALLERGY, ALLER-CORT, ASTELIN, ATROVENT, 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, FLUNISOLIDE 29 MCG-0.025% SPR, 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, VERAMYST, 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: Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
MEDICATION(S)
BUPHENYL, CARBAGLU, CERDELGA, MIGLUSTAT, RAVICTI, SODIUM PHENYL BUTYRATE, ZAVESCA

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 specialist in the respective disease state.

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

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

REAUTHORIZATION CRITERIA:
Both of the following must be met:
1. Documentation of successful response to therapy: AND
2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis (e.g., high-quality peer reviewed literature, guidelines, other clinical information)
MEDICATION(S)
ATOVAQUONE, MEPRON

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 13 years and older.

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

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

OTHER CRITERIA
For pneumocystis pneumonia (PCP): Documented trial, failure, intolerance or contraindication to trimethoprim/ sulfamethoxazole (TMP-SMX)

For Babesiosis:
1. Laboratory confirmation of infection (e.g., blood smear, PCR)
2. Documentation that the patient is experiencing symptoms of disease such as hemolytic anemia, thrombocytopenia, and/or flu-like symptoms
3. Confirmation that the patient will be taking atovaquone with azithromycin

Reauthorization: Most patients are able to be successfully treated after one 7-10-day treatment course. Subsequent treatments will require laboratory confirmation of continued infection (e.g., blood smear, PCR).
MEDICATION(S)
MIACALCIN 400 UNIT/2 ML VIAL

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-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:
      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
MEDICATION(S)
MILLIPRED, MILLIPRED DP, PREDNISOLONE 5 MG TABLET, 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
MEDICATION(S)
MIRCERA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hemoglobin and Hematocrit levels within 30 days prior to initiation of therapy.
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
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
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, ACANYA, ACTICLATE, ADAPALENE 0.1% LOTION, ADHANAX XR, ADOXA 150 MG CAPSULE, ADZENYS ER, ADZENYS XR-OĐT, AMPHETAMINE, AMPHETAMINE SULFATE, AMRIX, APLENZIN ER 348 MG TABLET, ASTEPRO, AZELASTINE 0.15% NASAL SPRAY, AZELASTINE-FLUTICASONE, BETAMETHASONE VALER 0.12% FOAM, BIDIL, BRYHALI, BUTALB-ACETAMIN-CAFF 50-300-40, 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, CLOBETASOL PROP 0.05% SPRAY, CLOBEX 0.05% SPRAY, COMBIGAN, CONSENSI, CONZIP, CUPRIMINE, CYCLOBENZAPRINE HCL ER, DAXBIA, DERMASORB HC, DERMASORB TA, DESLORATADINE 2.5 MG ODT, DESLORATADINE 5 MG ODT, DESONATE, DESONIDE 0.05% GEL, DESOXIMETASONE 0.25% SPRAY, DIFFERIN 0.1% LOTION, DORYX, DORYX MPC, DOXYCYCLINE 50 MG TABLET, DOXYCYCLINE HCY DR 100 MG TAB, DOXYCYCLINE HCY DR 150 MG TAB, DOXYCYCLINE HCY DR 200 MG TAB, DOXYCYCLINE HCY DR 50 MG TAB, DOXYCYCLINE HCY DR 75 MG TAB, DOXYCYCLINE HCY 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, EVEKEO ODT, EZALLOR SPRINKLE, FENOFIBRATE 150 MG CAPSULE, FENOFIBRATE 50 MG CAPSULE, FIORICET, FLO-PRED, FORTAMET, FOSAMAX PLUS D, GLUMETZA, GOCOVRI, GONITRO, GRALISE, HALOBETASOL PROP 0.05% FOAM, HYDROCORT BUTFY 0.1% LIPOP CREAM, HYDROCORT BUTFY 0.1% LIPO CREAM, HYDROCORTISONE BUTFY 0.1% LOTN, IMPOYZ, INDOMETHACIN 20 MG CAPSULE, JORNAY PM, KENALOG, KITABIS PAK, LEXETTE, LIDOVIX, LIPOFEN, LOC OID 0.1% LOTION, LOC OID LIPOCREAM, LORZONE, LUXIQ, LYRICA CR, METFORMIN ER GASTRIC, METFORMIN ER OSMOTIC, METOCLOPRAMIDE HCL ODT, METOPROLOL SUCCINATE ER-HCTZ, METIZOLV ODT, 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, OLEPTRO ER, OLMESARTAN-AMLODIPINE-HCTZ, OMEPPP, OMEPRAZOLE-SODIUM BICARBONATE, ONEXTON, ONMEL, ONZETRA XSAIL, ORACEA, ORBIVAN, OXYCODON-ACETAMINOPHEN 2.5-300, PENICILLAMINE 250 MG CAPSULE, PENNSAID, PHRENILIN FORTE 50-300-40 MG, 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, SOLOXIDE, SOLIXLUX, SPRITAM, SUMATRIPTAN SUCC-NAPROXEN SOD, TARGADOX, TELMISARTAN-AMLODIPINE, TIVORBEX, TOBRAMYCIN PAK
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 up to one year

OTHER CRITERIA
Requests are generally not approved because the requested drug is effective and available in the standard formulation. In unique circumstances, approval will 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. Zolpimist® will be limited to 1 container (60 doses of 5mg zolpidem) per 30 days for men (dose 5-10mg per day), and 60 days for women (dose 5mg per day).
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 rosvastatin 40 mg daily
   b. Documented statin intolerance to low dose atorvastatin or rosvastatin (atorvastatin 10 mg daily or rosvastatin 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
MEDICATION(S)
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 initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be for two months. Reauthorization will be for six months.

OTHER CRITERIA
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.
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
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 will be approved for 6 months, reauthorization will be approved for 1 year

OTHER CRITERIA
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
MEDICATION(S)
NPLATE

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

COVERAGE DURATION
Initial authorization will be approved for up to 3 months. Reauthorization will be approved for up to 6 months.

OTHER CRITERIA
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 30 x 109/L
   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 dose below 10 mcg/kg.
QUANTITY LIMITS:
Nplate is available as 250mcg and 500mcg vials of lyophilized powder. Quantity approved may be rounded down to nearest available vial size within 10% of calculated dose.
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

M EDICATION(S)
NUCYNTA ER

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

E XCLUSION CRITERIA
As needed (prn) use

R EQUIRED 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)

Q UANTITY LIMIT:
Limit to 60 tablets per 30 days.

A GE RESTRICTION
N/A

P RESCRIBER RESTRICTION
N/A

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

O THER CRITERIA
N/A
NUDEXTA

MEDICATION(S)
NUDEXTA

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
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
MEDICATION(S)
OCALIVA

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

EXCLUSION CRITERIA
Use for non-alcoholic steatohepatitis (NASH)

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
1. Confirmed diagnosis of Primary Biliary Cholangitis with two of three of the following criteria met:
   a. Elevated alkaline phosphatase elevation (greater than ULN)
   b. Presence of antimitochondrial antibody (AMA) (titer greater than or equal to 1:40)
   c. Liver biopsy consistent with primary biliary cirrhosis
   AND
2. Both of the following:
   a. Use of ursodiol for a minimum of 6 months and failure to achieve: alkaline phosphatase (ALP) less than or equal to 1.5 X ULN, aspartate aminotransferase (AST) less than or equal to 1.5 X ULN, and total bilirubin (tBili) less than or equal to ULN. If laboratory reference values for ALP are not available, the values used in a clinical trial may be used for this assessment (ULN = 117 U/L for women: 129 U/L for men).
   AND
b. Documentation that ursodiol will be continued unless there were intolerable adverse effects with 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 (ie. alkaline phosphatase (ALP) less than or equal to 1.67 times ULN, total bilirubin (tBili) less than or equal to ULN, and an 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
OPHTHALMIC VEGF INHIBITORS: EYLEA, LUCENTIS, MACUGEN

MEDICATION(S)
BEOVU, EYLEA, LUCENTIS, MACUGEN

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 and administered by an ophthalmologist or retinal specialist

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

OTHER CRITERIA
Initial Authorization:
Must have one of the following diagnoses and meet any required criteria:

1. Neovascular (wet) age-related macular degeneration (AMD)
For ranibizumab (Lucentis®), aflibercept (Eylea®), brolucizumab (Beovu®)
   a. 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
   b. Rationale is provided why therapy with bevacizumab (Avastin®) is not appropriate for the patient

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

2. Diabetic macular edema or Diabetic retinopathy
For ranibizumab (Lucentis®) or aflibercept (Eylea®):
   a. 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
   b. Request is for aflibercept (Eylea®) and patients baseline visual acuity is 20/50 or worse
   OR
   c. Rationale is provided why therapy with bevacizumab (Avastin®) is not appropriate for member

3. Macular edema following retinal vein occlusion
For ranibizumab (Lucentis®) or aflibercept (Eylea®):
   a. 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
   b. 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.
(See Table 1 for dosing guidelines)
ORAL ANTI-CANCER MEDICATIONS

**MEDICATION(S)**
ABIRATERONE ACETATE, AFINITOR, AFNITIOR DISPERZ, ALECENSA, ALKERAN 2 MG TABLET, ALUNBRIG, AYVAKIT, BALVERSA, BEXAROTENE, BOSULIF, BRAFTOVI, BRUKINS, CABOMETYX, CALQUIENCE, CAPRELSA, COMETRIO, COPIKTRA, COTELIC, DAURISMO, ERIVEDGE, ERLEADA, EROTONIB HCL, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, FARYDAK, GILOTRIF, GLEEVEC, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA, INLYTA, INCREC, IRESSA, JAKAFI, KISQALI, KISQALI FEMARA CO-PACK, LENVIMA, LONSURF, LORBRENA, LYNPARZA, MEKINIST, MEKTOVI, MELPHALAN, NERLYNX, NEXAVAR, NINLARO, NUBEQA, ODOMZO, PIQRAY, POMALYST, REVLIMID, ROZLYTREK, RUBRACA, RYDAPT, SPRYCEL, STIVARGA, SUTENT, TAFINLAR, TAGRIS, 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, TEOZOLOMIDE, TIBSOVO, TRETINOIN 10 MG CAPSULE, TURALIO, TYKERB, VANDETANIB, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VESANOID, VITRAKVI, VIZIMPRO, VOTRIENT, XALKORI, XOSPATA, XPOVIO 100 MG ONCE WEEKLY DOSE, XPOVIO 60 MG ONCE WEEKLY DOSE, XPOVIO 80 MG ONCE WEEKLY DOSE, XPOVIO 80 MG TWICE WEEKLY DOSE, XTANDI, YONSA, ZEJULA, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA, ZYTIGA

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

For off-label use criteria, please see the Chemotherapy Treatment Utilization Criteria: Coverage for Non-FDA Approved Indications ORPTCOPS105.

**EXCLUSION CRITERIA**
N/A

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

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Must be prescribed by, or in consultation, with an oncologist.
COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
For initial authorization:
1. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

   AND

2. For commercial members only, the following drug-specific criteria must be met:
   a. For ribociclib (Kisqali®) for advanced or metastatic breast cancer: Documented trial, failure, intolerance or contraindication to palbociclib (Ibrance®) or abemaciclib (Verzenio®)
   b. For talazoparib (Talzenna®) for recurrent or metastatic breast cancer: Documented trial, failure, intolerance or contraindication to olaparib (Lynparza®)
   c. For niraparib (Zejula®) for recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer with a complete or partial response to platinum-based chemotherapy: Documented trial, failure, intolerance or contraindication to olaparib (Lynparza®) or rucaparib (Rubraca®)

For reauthorization: documentation of adequate response to the medication must be provided.
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
Sjogren’s syndrome

EXCLUSION CRITERIA
Other indications not outlined above

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 3 months.

OTHER CRITERIA
1. The patient must have ONE of the following diagnoses:
   a. Mucositis/stomatitis secondary to chemotherapy or radiation
   b. Xerostomia secondary to chemotherapy or radiation
   c. Sjogren’s syndrome
   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)
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
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, psychiatrist, or expert in the treatment of movement disorders

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

OTHER CRITERIA
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
OXAYDO/ROXYBOND

MEDICATION(S)
OXAYDO, OXECTA, 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
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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 6 months
   b. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least 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 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 6 months and reauthorization will be approved for 1 year

OTHER CRITERIA
N/A
OXERVATE

MEDICATION(S)
OXERVATE

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

EXCLUSION CRITERIA
Retreatment of the same eye

REQUIRED MEDICAL INFORMATION
Documentation of which eye will be treated.

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

AGE RESTRICTION
N/A

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

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

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

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

MEDICATION(S)
OPANA, OXYMORPHONE HCL

COVERED USES
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
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
PARENTERAL NUTRITION (TPN) - MEDICAID

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, FREAMINE HBC, FREAMINE III, HEPATAMINE, INTRALIPID, NEPHRAMINE, NUTRILIPID, OMEGAVERN, PLENAMINE, PREMASOL, PROCALAMINE, PROSOL, SMOFLIPID, SYNTHAMIN 17 WITHOUT ELTYE, TRAVASOL, TROPHAMINE

COVERED USES
N/A

EXCLUSION CRITERIA
Coverage for IDPN when offered in addition to regularly scheduled TPN infusions

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization approved for 3 months and re-authorizatio will be approved for up to one year.

OTHER CRITERIA
One of the following criteria must be met:
1. Member has a central or peripheral line placed within the past 3 months 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.
PCS9 INHIBITORS

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

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
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 rosvastatin (Crestor®) 40 mg daily,
   OR
2) Documented statin intolerance to low dose atorvastatin or rosuvastatin (atorvastatin 10 mg daily or rosuvastatin (Crestor®) 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 (Zetia®) 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), confirmed diagnosis by one of the following:
      i. 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
      ii. Low density lipoprotein cholesterol (LDL-C) greater than 330 mg/dL
      OR
      iii. LDL-C greater than 190 mg/dL and two of the following:
          1) Presence of tendon xanthomata in patient or in first- or second-degree relatives
          2) Personal history of premature atherosclerotic cardiovascular disease (ASCVD) in men less than 55 years or women less than 60 years
          3) First-degree relative with premature ASCVD (men less than 55 years, women less than 60 years)
   b. For hyperlipidemia, documentation of one of the following LDL-C level and cardiovascular risk combinations. LDL-C levels must be taken after at least 3 months of continuous therapy with statin and ezetimibe outlined in criterion 1 above, and within the previous 6 months:
      i. LDL-C greater than 70 mg/dL and history of clinical ASCVD, defined as one of the following: non-ST segment elevation myocardial infarction (NSTEMI), myocardial infarction, unstable angina, coronary revascularization, or clinically significant multi-vessel coronary heart disease
      ii. LDL-C of greater than 100 mg/dL and of one of the following risk factors:
          1. Peripheral artery disease
          2. History of ischemic stroke
          3. Chronic kidney disease
          4. Diabetes mellitus with at least two additional cardiovascular risk factors (e.g., hypertension, retinopathy, or family history of premature cardiovascular disease)

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
PEDiatric ANALGESICS

MEDICATION(S)
ACETAMINOPHEN-CODEINE, ASA-BUTALB-CAFFEINE-CODEINE, ASCOMP WITH CODEINE,
BUTALB-ACETAMINOPH-CAFF-CODEIN, BUTALB-CAFF-ACETAMINOPH-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, ROBAFEN AC,
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,
TUZISTA XR, TYLENOL-CODEINE NO.3, TYLENOL-CODEINE NO.4, ULTRACET, ULTRAM, ULTRAM
ER, 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
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

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

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A
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
Potassium 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.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization: 6 months
Reauthorization: 12 months

OTHER CRITERIA
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)
PREVYMIS

MEDICATION(S)
PREVYMIS

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 a hematologist, oncologist, or Infectious Disease specialist.

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

OTHER CRITERIA
ALL of the following must be met:
1) Member is within 100 days post-allogeneic transplant: and
2) Cytomegalovirus (CMV) Recipient positive: and
3) Member has ONE of the following:
   a) Graft Versus Host Disease (GVHD) requiring greater than or equal to 1 mg/kg/day use of prednisone [or equivalent]
   b) Receipt of lymphocyte depleting therapy (e.g. antithymocyte globulin [ATG], antithymocyte globulin equine [ATGAM], antithymocyte globulin rabbit [thymoglobulin], alemtuzumab, fludarabine) within the previous 6 months
   c) Transplant was a cord blood allograft
   d) History of CMV drug resistance within the past 6 months
4) If IV lettermovir is being requested, rationale for not using oral formulation must be provided (e.g. patient is unable to swallow)
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
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
1 year of age and older

PRESCRIBER RESTRICTION
N/A

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

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

MEDICATION(S)
PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET

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

OTHER CRITERIA
For initiation of therapy, one of the following criteria must be met:
1. Documentation that medically necessary dose of tacrolimus cannot be achieved through use of generic tacrolimus capsules (which are available in 0.5, 1, and 5 mg strengths) OR
2. Documentation that the patient has difficulty swallowing generic tacrolimus capsules
PROMACTA

MEDICATION(S)
PROMACTA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Platelet Count

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

AGE RESTRICTION
N/A

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

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

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

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

For Reauthorization for ITP or severe aplastic anemia:
Platelet levels demonstrating response to therapy as well as documentation that eltrombopag continues to be required to maintain a platelet count of at least $50 \times 10^9$ per liter.
PROVENGE - MEDICAL BENEFIT

MEDICATION(S)
PROVENGE

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

EXCLUSION CRITERIA
Concomitant use of chemotherapy and/or immunosuppressive medication with sipuleucel-T is considered experimental/investigational and 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
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
All of the following criteria must be met:
1. Asymptomatic or minimally symptomatic metastatic disease (e.g. no complaints of bone pain, no narcotic use for malignant cancer pain)
2. Castrate-resistant or castration-recurrent prostate cancer, defined as both of the following:
   a. Radiographic progression despite therapy with androgen ablation therapy (e.g. orchiectomy, GnRH agonists/antagonists)
   AND
   b. Testosterone level less than 50 ng/dL
3. No evidence of hepatic metastases
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
5. Life expectancy greater than 6 months
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
1. Pulmonary arterial hypertension (PAH)
2. Chronic Thromboembolic Pulmonary Hypertension (CTEPH) for Adempas® only

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist or cardiologist

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

OTHER CRITERIA
For initial authorization the following criteria must be documented:
1. Diagnosis of Pulmonary Arterial Hypertension (PAH) confirmed by right heart catheterization as defined by:
   A. Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest AND
   B. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHg
AND
C. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU)
AND
2. Patient has documented World Health Organization (WHO) Group 1 classification PAH (or WHO Group 4 classification CTEPH for Adempas® only) with WHO/New York Heart Association (NYHA) functional class as outlined below:
   A. Flolan®, Veletri®, and Ventavis: Class III or IV
   B. Tyvaso®: Class III or IV
   C. All other therapies: Class II, III, or IV
AND
3. For sildenafil citrate oral suspension or 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 - A one-time fill will be allowed for the Uptravi® Titration pack for initial dose titration
• Tadalafil (Adcirca®): 2 tablets/day
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
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 seizure disorders
1. Documentation of trial and failure, intolerance or contraindication to topiramate immediate release AND one additional formulary anti-epileptic medication: e.g. valproic acid, clonazepam or lamotrigine.
OR
2. Prescriber is a Neurologist.

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

An adequate trial and failure is defined as minimal to no improvement after at least three (3) months of therapy.
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
Forced vital capacity (FVC), completed ALS Functional Rating Scale-Revised (ALSFRS-R) score form (see Appendix 1) take at baseline and current functional ability in activities of daily living (ADLs)

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 Neurologist with expertise in ALS.

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

OTHER CRITERIA
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 2 points in each individual item (Use Appendix 1)
   d. Forced vital capacity (FVC) greater than 80% (taken within the past 3 months)

Reauthorization criteria:
1. Documentation of a clinical benefit from therapy such as stabilization of functional ability and
maintenance of ADLs

2. Patient must not have more than a 6 point decline in the ALSFRS-R from baseline
REBLOZYL

MEDICATION(S)
REBLOZYL

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

EXCLUSION CRITERIA
Evidence of active pregnancy
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 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, intolerance, or contraindication to erythropoiesis-stimulating agents (i.e., erythropoietin or darbepoetin)
   b. Documentation of endogenous erythropoietin level greater than 200 IU/L

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 1 year.
MDS-RS: Initial authorization will be for 6 months. Reauthorization will be for 1 year.

OTHER CRITERIA
N/A
REGRANEX

MEDICATION(S)
REGRANEX

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 one reauthorization will be approved for 90 days.

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

For reauthorization for a second 90 day course, must submit documentation showing an adequate
response defined by a 30% reduction or greater in ulcer size. There is no medical evidence to justify ongoing treatment after 180 days of Regranex® treatment.
MEDICATION(S)
RELISTOR

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

For Medicaid: Constipation is considered “below the line”. Therefore, coverage is dependent on whether the constipation adversely affects, or is secondary 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.

The following condition(s) are not covered:
• Opioid-induced constipation in patients with non-cancer pain

EXCLUSION CRITERIA
• Non-opioid induced constipation
• Known or suspected gastrointestinal obstruction not limited to:
  o Acute surgical abdomen
  o Fecal impaction
  o Acute diverticular 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
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization for 1 year.

OTHER CRITERIA
1. Patient is on chronic opioid therapy
   AND
2. Documentation of less than 3 spontaneous bowel movements per week
3. **Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) 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. One (1) of the following prescription medications
      i. Naloxegol (Movantik®)
      ii. Lubiprostone (Amitiza®)
      iii. Naldemedine (Symproic®)

**For Medicaid, please note that chronic constipation secondary to continuous opioid use as part of a palliative care regimen, or for treatment of active cancer pain, is approvable without meeting criterion #3 only if medical rationale is sufficient**

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
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
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
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 10^9/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
MEDICATION(S)
RITUXAN, RITUXAN HYCELA, RUXIENCE, TRUXIMA

COVERED USES
All Food and Drug Administration (FDA) approved Indications not otherwise excluded from the benefit. May also be covered for vasculitis, immune thrombocytopenia (ITP), relapsing and remitting multiple sclerosis (RRMS), refractory myasthenia gravis, autoimmune hemolytic anemia (AIHA), and neuromyelitis optica (NMO) subject to criteria.

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 two (2) 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 DMARD (e.g., leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy.

Reauthorization requires documentation of adequate response to therapy.

For Vasculitis – including 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 x 10^9/L
For Relapsing and Remitting Multiple Sclerosis (RRMS):
1. Documentation of trial, failure, intolerance, or contraindication to one (1) injectable disease modifying agent which include: interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®, Rebif®), glatiramer (Copaxone®, Glatopa®)
AND
2. Documentation of trial, failure, intolerance, or contraindication to at least two (2) oral preferred disease modifying agents which include: dimethyl fumarate (Tecfidera®), fingolimod (Gilenya®), teriflunomide (Aubagio®)

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
      AND
   b. Documentation that the patient is unable to achieve remission with splenectomy unless the patient is not a candidate for surgery
      OR
   2. In patients diagnosed with cold AIHA or cold agglutinin disease

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 and reauthorization will be approved for six months

OTHER CRITERIA
MEDICATION(S)
SABRIL, VIGABATRIN, VIGADROME

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
For complex partial seizures: approved for ages 10 years and older.

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

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

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

OTHER CRITERIA
Must be prescribed by, or in consultation with, a neurologist

For refractory complex partial seizures:
1. Must be at least 10 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’ old
SANDOSTATIN / SANDOSTATIN LAR

MEDICATION(S)
OCTREOTIDE ACETATE, SANDOSTATIN, SANDOSTATIN LAR, 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 and chemotherapy-induced diarrhea, oncologic conditions.

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
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
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 varices 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
**MEDICATION(S)**
SCENESSE

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

**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 > 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 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, SM ALL DAY ALLERGY 1 MG/ML SYR, 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 10 MG SFTGL, 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 1 MG/ML SOLN, EQ ALLERGY RELIEF 180 MG TAB, GNP 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 1 MG/ML SOLN, CETIRIZINE HCL 1 MG/ML SYRUP, CETIRIZINE HCL 10 MG CHEW TAB, CETIRIZINE HCL 5 MG CHEW TAB, CETIRIZINE HCL 5 MG/5 ML SOLN, CETIRIZINE-PSEUDOEPHEDRINE ER, CHILDREN'S ALL DAY ALLERGY, CHILDREN'S ALLEGRA ALLERGY, PUB CHILDREN'S ALLERGY 1 MG/ML, QC CHILDREN'S ALLERGY 1 MG/ML, CHILD ALLERGY RELIEF 1 MG/ML, CVS CHILD ALLERGY RELF 1 MG/ML, CVS CHILD ALLERGY RLF 30 MG/5, EQ CHILD ALLERGY RELF 1 MG/ML, RA CHILD ALLERGY RELF 1 MG/ML, CHILDREN'S CETIRIZINE HCL, CHILDREN'S WAL-FEX, CHILDREN'S WAL-ZYR, CHILDREN'S ZYRTEC, 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, SM LORATADINE 10 MG ODT, 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 SOLUTION, WAL-ZYR D, XYZAL, ZYRTEC 10 MG LIQUID GELS, ZYRTEC 10 MG ODT, ZYRTEC-D

COVERED USES
Allergic rhinitis allergic conjunctivitis, or chronic rhinitis/pharyngitis/nasopharyngitis when a co-morbidity affected by difficult breathing exists, as outlined in criteria below.

EXCLUSION CRITERIA
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, QTERN, STEGLATRO, STEGLUJAN, XIGDUO XR

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

EXCLUSION CRITERIA
Type 1 diabetes

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
N/A

COVERAGE DURATION
Initial authorization and reauthorization for 1 year

OTHER CRITERIA
Initial authorization:
All the following criteria are required:
1. Documentation of trial and failure*, contraindication or intolerance to metformin therapy at the maximum effective dose of 2000 mg/day
   AND
2. A documented HbA1c, obtained within the last six months, which is greater than or equal to 7% and less than or equal to 10%.
   AND
3. Documented trial and failure* to one of the following medication classes, or intolerance/contraindication to all classes listed below. If the patient has history of cardiovascular disease, this criterion may be waived.
   a. Sulfonylurea (e.g., glimepiride, glyburide)
b. Thiazolidinedione (e.g., pioglitazone)
AND
4. Documented trial and failure*, contraindication or intolerance to empagliflozin (Jardiance®)

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

Reauthorization:
Requires that the HbA1c remains less than or equal to 9%.
MEDICATION(S)
SIGNIFOR

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 will be approved for three months and reauthorization will be approved for one year

OTHER CRITERIA
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)
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)
MEDICATION(S)
SIMVASTATIN 80 MG TABLET, ZOCOR 80 MG TABLET

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 for 12 months.

OTHER CRITERIA
Documentation demonstrating that member has been maintained on simvastatin 80 mg for 12 months or more without evidence of muscle toxicity.
SOLIRIS - MEDICAL BENEFIT

MEDICATION(S)
SOLIRIS

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

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), NCCN, or Drugdex and is considered subject to evaluation of the prescriber’s medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

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
PNH or aHUS: Prescribed by an Hematologist/Oncologist or Nephrologist
MG or NMOSD: Prescribed by a Neurologist

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

OTHER CRITERIA
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 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):

AND
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 (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

Reauthorization for PNH: documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms

For Complement-Mediated Hemolytic Uremic Syndrome (HUS), all of the following must be met:
1. Diagnosis of non-infections 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. Complement 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)

Reauthorization for HUS: 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 plasmapheresis or plasma infusion events
- Improvement in kidney function and reduction of dialysis

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 1 year with the following:
A. At least TWO immunosuppressive therapies ([ISTs] such as azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus, corticosteroids)

OR

B. ONE immunosuppressive therapy and required at least 4 infusions/ year of either intravenous immunoglobulin (IVIg) OR plasma exchange (PE)

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

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

Reauthorization for Neuromyelitis Optica Spectrum Disorder (NMOSD): Documentation of positive clinical response to therapy
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
MEDICATION(S)
SPINRAZA

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

EXCLUSION CRITERIA
Concomitant use with, or following, gene therapy for SMA (e.g., onasemnogene abeparvovec)

REQUIRED MEDICAL INFORMATION
Genetic test results (“survival motor neuron (SMN)1 gene testing”/“spinal muscular atrophy (SMA) diagnostic test”)

Documentation of baseline motor function, with a standardized test deemed appropriate based on the patient’s age and level of function: CHOP-INTEND, HINE, HFMSE, RULM, or 6MWT

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 neurologist

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

OTHER CRITERIA
1. Diagnosis of Spinal Muscular Atrophy w/ genetic testing confirmation
   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

Reauthorization: Improvement or maintenance of motor function, evidenced by follow-up results of motor function test performed at baseline
MEDICATION(S)
ADDERALL 5 MG TABLET, ADDERALL XR, APTENSIO XR, CONCERTA, COTEMPLA XR-ODT, DAYTRANA, DEXEDRINE SPANSULE 10 MG, DEXEDRINE SPANSULE 15 MG, DEXEDRINE SPANSULE 5 MG, DEXMETHYLPHENIDATE HCL ER, DEXTROAMPHETAMINE SULFATE ER, DEXTROAMPHETAMINE-AMPHET ER, DEXTROAMP-AMPHETAMINE 5 MG TAB, 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
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

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

OTHER CRITERIA
1. Continuity of care will be honored if member has demonstrated being established (within the last year) on a formulary or non-formulary long-acting stimulant medication OR
2. For adult members (18 years of age or older):
   a. For narcolepsy, formulary long-acting stimulant medications will be covered with a confirmed diagnosis supported by clinical documentation
      OR
   i. For request of non-formulary long-acting stimulant medications, documented trial and failure (minimum of 4 weeks), intolerance or contraindication to at least two formulary long-acting stimulant medications (see table 1)
      OR
   b. For request of lisdexamphetamine (Vyvanse®):
      i. Binge eating disorder: will be covered with a confirmed diagnosis supported by clinical documentation
      OR
   c. For Attention Deficit Hyperactivity Disorder (ADHD), member must meet criteria 2ci or 2cii below:
      i. Confirmed diagnosis of adult ADHD defined as the following made in an evidence-based fashion supported by clinical documentation in accordance with Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria
         1. Five or more symptoms of inattention or hyperactivity and impulsivity have persisted for at least six months to a degree that is maladaptive (see Appendix 1 for DSM-5 ADHD overview)
            AND
         2. Several inattentive or hyperactive-impulsive symptoms were present prior to age 12 years
            AND
         3. Several inattentive or hyperactive-impulsive symptoms are present in two or more settings (e.g., at home, school, or work: with friends or relatives: in other activities)
            OR
      ii. Confirmed diagnosis of adult ADHD made in an evidence-based fashion by a psychiatrist or in conjunction with a behavioral health consult
            AND
      iii. For request of formulary long-acting stimulant medications, documented trial and failure (minimum of 4 weeks), intolerance or contraindication to at least two formulary immediate-release stimulant medications (see table 1)
            AND
      iv. For request of non-formulary long-acting stimulant medications, documented trial and failure (minimum of 4 weeks), intolerance or contraindication to at least two formulary immediate-release stimulant medications and two formulary long-acting stimulant medications (see table 1)

QUANTITY LIMIT:
All long-acting formulation of stimulant medications are covered at one tablet/capsule per day.
Exception:
• Adderall XR® (dextroamphetamine-amphetamine ER) 20mg capsules (2 capsules per day)
• Concerta® (methylphenidate ER) 36mg (2 tablets per day if formulary exception prior authorization is approved)
If requested quantities exceed formulary quantity limit, additional criteria will apply. Please refer to Medical Policy #ORPTCCNS029 - Long-Acting Stimulant Medications Quantity Limit.
**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 at 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
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
These allergen extracts must be prescribed by or in consultation with an Allergist, an Immunologist, an Otolaryngologist, or other physician currently providing subcutaneous immunotherapy to patients in their practice.

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

OTHER CRITERIA
For treatment with sublingual immunotherapy, patients must meet all the following for initial authorization:
1. Diagnosis of allergic rhinitis, with or without conjunctivitis
   AND
2. Documentation that member remains symptomatic despite treatment with both of the following:
   a) An intranasal steroid
   b) An oral anti-histamine
   AND
3. Documentation that the sublingual immunotherapy will begin at least 12 weeks (for Grastek® or Ragwitek®) or 14 weeks (for Oralair®) before the start of the allergy season
   AND
4. Documentation of a positive skin test or pollen specific antibodies to the relevant allergen:
   a) Grastek: Timothy grass or cross-reactive grass
   b) Oralair: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass
   c) Ragwitek: Short Ragweed
   d) Odactra: House dust mite
   AND

5. Subcutaneous immunotherapy will not be used concurrently

For reauthorization: Consistent use during treatment period for allergy season previously approved for coverage

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

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

MEDICATION(S)
SUCRAID

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

EXCLUSION CRITERIA
Treatment of secondary (acquired) disaccharide deficiencies

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

AGE RESTRICTION
N/A

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

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

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

AGE RESTRICTION
N/A

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

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

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
1. Documentation of trial and failure, contraindication, or intolerance to clobazam tablets or suspension. AND
2. Documentation of trial and failure, contraindication, or intolerance to two (2) alternative generic formulary agents (i.e. valproic acid, lamotrigine, topiramate, felbamate)
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
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

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

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

MEDICATION(S)
VYNDAMAX, VYNDAQEL

COVERED USES
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, inotersen)

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

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

AGE RESTRICTION
Approved for patients 18 years of age and older

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

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

OTHER CRITERIA
Initial authorization:
1. Documentation of genetic testing results for mutations of the transthyretin (TTR) gene (patient may have a genetic variation or be wild type)
2. Confirmation of amyloid deposits showing cardiac involvement by ONE of the following:
   a. A positive 99mTechnetium-Pyrophosphate (99mTc-PYP) scan
   b. A positive cardiac biopsy for ATTR amyloid
   c. A positive non-cardiac biopsy for ATTR amyloid and evidence of cardiac involvement by evidence of
cardiac involvement by end-diastolic interventricular septal wall thickness greater than 12 mm (by echocardiogram or MRI) or suggestive cardiac MRI findings
3. Documentation of patient’s NYHA functional class (functional class IV is excluded from coverage)
4. Documentation of clinical signs or symptoms of cardiomyopathy and/or heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema, elevated BNP or NT-BNP levels)
5. Documentation of baseline 6-minute walk test or Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS)

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

QUANTITY LIMIT:
Tafamidis meglumine capsule (Vyndaqel®): 4 capsules per day
Tafamidis capsule (Vydamax®): 1 capsule per day
MEDICATION(S)
TAVALISSE

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Recent platelet counts

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

AGE RESTRICTION
Approved for 18 years of age and older.

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

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

OTHER CRITERIA
Initial authorization:
1. Diagnosis of chronic immune thrombocytopenia (ITP)
2. Platelet count of less than 30,000/uL
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 /uL or greater
QUANTITY LIMIT:
Fostamatinib Disodium (Tavalisse®) 100 and 150 mg tablets: 2 per day
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
MEDICATION(S)
ANDRODERM, ANDROGEL 1.62% GEL PUMP, ANDROGEL 1.62%(1.25G) GEL PCKT, ANDROGEL 1.62%(2.5G) GEL PCKT, AVEED, AXIRON, 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 (hypogonadotropic) 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, CIMZIA, COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE, ENBREL 25 MG KIT, ENBREL 25 MG/0.5 ML SYRINGE, ENBREL 50 MG/ML SYRINGE, 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 PSOR-UV-ADOL HS, 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
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
• Below the line diagnoses
• Combination therapy with another therapeutic immunomodulator (TIM) agent or apremilast (Otezla®)

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

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

OTHER CRITERIA
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. 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 DMARDs
      2. For non-preferred TIMs agent:
         a. Documented adequate trial and failure?, intolerance or contraindication to at least one of the following preferred TIMs agents: adalimumab (Humira®), etanercept (Enbrel®), or infliximab biosimilar (Inflectra® or Renflexis®)
            AND
         b. If patient has satisfied criteria above (i.2.a.), documented trial, failure, intolerance or contraindication to tofacitinib (Xeljanz®/Xeljanz XR®)
      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?, intolerance or contraindication to at least two of the following TIMs agents: adalimumab (Humira®), infliximab biosimilar (Inflectra® or Renflexis®) 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?, 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?, intolerance or contraindication to the following preferred agents:
      a. One of the following agents: adalimumab (Humira®), etanercept (Enbrel®) or infliximab biosimilar (Inflectra® or Renflexis®)
      AND
      b. If patient has satisfied criteria above (iii.3.a.), documented trial, failure, intolerance or contraindication to apremilast (Otezla®)

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?, intolerance or contraindication to the following preferred agents:
      a. One of the following agents: adalimumab (Humira®), etanercept (Enbrel®) or infliximab biosimilar (Inflectra® or Renflexis®)
      AND
      b. If patient has satisfied criteria above (iv.3.a.), documented trial and failure?, 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?, intolerance or contraindication to at least one of the following preferred agents: adalimumab (Humira®), etanercept (Enbrel®) or infliximab biosimilar (Inflectra® or Renflexis®)
vi. For giant cell arteritis:
1. Documentation of trial and failure?, intolerance, or contraindication to at least one conventional therapy (e.g., systemic corticosteroid therapy)
vii. For Non-radiographic axial spondyloarthritis: certolizumab (Cimzia®) may be covered

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

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

*apremilast is FDA approved for psoriasis and psoriatic arthritis

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

Exception: For Crohn's Disease, Stelara® may be approved for FDA labeled dosing for this condition (90
mg every 8 weeks)
MEDICATION(S)
THIOLA, THIOLA EC

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
24-hour urine collection with urinary cysteine levels

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

AGE RESTRICTION
N/A

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

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

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

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

MEDICATION(S)
JYNARQUE, SAMSCA, TOLVAPTAN

COVERED USES
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 diagnosis 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)
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-mediated amyloidosis with cardiomyopathy
• Others forms of amyloidosis that is not due to a genetic mutation in the TTR gene
• Patients without the presence of polyneuropathy symptoms associated with hATTR amyloidosis
• Patients with type I or type II diabetes
• Previous organ transplant(s) requiring immunosuppression
• Malignancy within the past five years
• Uncontrolled cardiac arrhythmia or unstable angina

REQUIRED MEDICAL INFORMATION
• Genetic test results (TTR gene testing documenting mutation)
• Documentation of baseline polyneuropathy and impairment demonstrated by the following three (3) standardized tools:
  1. Polyneuropathy disability (PND) score OR familial amyloid polyneuropathy (FAP) stage
  2. Neuropathy impairment score (NIS)
  3. Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score

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

AGE RESTRICTION
Approved for patients 18 years of age and older

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

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

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

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

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

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, viral load, resistance testing 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 as well as viral load.

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 1 year.

OTHER CRITERIA
Initial Authorization:
1. Inadequate response to six (6) months of treatment with anti-retroviral therapy (ART) and have failed therapy within the last 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™ 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™ therapy.
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
Anti-JCV antibody. For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by either a Neurologist or Gastroenterologist.

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

OTHER CRITERIA
For Multiple Sclerosis:
1. Clinical diagnosis of a relapsing form of multiple sclerosis
AND
2. One of the following:
a. Documentation of trial, failure, or intolerance to at least two of the following disease modifying therapies: interferon beta-1a (Avonex®, Rebif®), peginterferon beta-1a (Plegridy®), interferon-beta 1b (Betaseron®), dimethyl fumarate (Tecfidera®), glatiramer acetate (Copaxone®), teriflunomide (Aubagio®), or fingolimod (Gilenya®)
OR
b. Documentation that patient has highly active or aggressive disease
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, 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-α 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
UCERIS

MEDICATION(S)
BUDESONIDE ER, UCERIS

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 patients 18 years and older.

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
For budesonide extended release tablets (Uceris®)
1. Documented trial, failure, intolerance or contraindication to treatment with an aminosalicylate (e.g., sulfasalazine, mesalamine)
AND
2. Documented trial, failure, intolerance or contraindication to one of the following oral corticosteroids: dexamethasone, hydrocortisone, methylprednisolone, prednisone or budesonide extended release capsule

For budesonide foam (Uceris®):
1. Documented trial, failure, intolerance or contraindication to a rectal mesalamine product
AND
2. Documented trial, failure, intolerance or contraindication to a rectal steroid product (i.e hydrocortisone rectal enema)

The initial approval of Uceris® tablets and foam will allow for an 8-week treatment course. Further approval
for Uceris® requires medical rationale why additional treatment is warranted and if patient is not on maintenance therapy for ulcerative colitis why it is not appropriate.
ULTOMIRIS

MEDICATION(S)
ULTOMIRIS

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
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
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 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)
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

For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®) for PNH:
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.

Reauthorization: 
Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms

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)

For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®)
Confirmed documentation of Compliment-Mediated Hemolytic Uremic Syndrome (criteria 1, 2 and 3). However, this can be based on patient’s history prior to starting eculizumab.

Reauthorization for HUS: 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
**VASCEPA**

**MEDICATION(S)**
VASCEPA

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

**EXCLUSION CRITERIA**
N/A

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

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

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

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

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

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

b. Diabetes mellitus and two or more of the following additional risk factors for cardiovascular disease:
   i. Men equal to or greater than 55 years of age or women equal to or greater than 65 years of age
   ii. Hypertension
   iii. High-density lipoprotein cholesterol (HDL-C) equal to or less than 40 mg/dL for men or equal to or less than 50 mg/dL for women
   iv. High-sensitivity C-reactive protein (hs-CRP) greater than 3.0 mg/dL
   v. Reduced kidney function (eGFR less than 60 mL/min per 1.73m²)
   vi. Current cigarette smoker or recently quit smoking cigarettes within the past 3 months
   vii. Retinopathy
   viii. Micro- or macro-albuminuria
   ix. Ankle-brachial index less than 0.9 without symptoms of intermittent claudication

2. Current use of a high-intensity statin therapy for at least 4 weeks or documented statin intolerance at any dose. Statin intolerance is defined as intolerable muscle side effects or biomarker changes (such as elevations of creatinine kinase) that decrease or resolve after discontinuation of therapy with statin.

3. A triglyceride level within the past 6 months that is equal to or greater than 150 mg/dL.

4. A low-density lipoprotein cholesterol (LDL-C) level within the past 6 months that is less than or equal to 100 mg/dL.
VEREGEN

MEDICATION(S)
VEREGEN

COVERED USES
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
N/A

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

OTHER CRITERIA
Documented trial, failure, intolerance, or contraindication to imiquimod 5% cream packets (Aldara®).
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
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A
VMAT2 INHIBITORS

MEDICATION(S)
AUSTEDO, 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 and/or untreated or inadequately treated depression
• Hepatic Impairment
• Use in combination with monoamine oxidase inhibitors, other VMAT2 inhibitors or reserpine

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 or Psychiatrist.

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

OTHER CRITERIA
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.

Reauthorization: Documentation showing benefit of therapy with improved function through reduction of 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
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
MEDICATION(S)
EZETIMIBE-SIMVASTATIN, VYTORIN

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

OTHER CRITERIA
Documented trial and failure of atorvastatin 80 mg and rosuvastatin 40 mg daily.
AND
For Vytorin® 10 mg/80 mg only: Documentation demonstrating that member has been maintained on therapy for 12 months or more of simvastatin 80 mg without evidence of muscle toxicity
MEDICATION(S)
WAKIX

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

EXCLUSION CRITERIA
Idiopathic central nervous system hypersomnia

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. Full nocturnal polysomnogram and a multiple sleep latency test.

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
Initial Authorization:
All of the following criteria must be met:
1. Diagnosis of narcolepsy as confirmed by one of the following:
   a. The patient has a Multiple Sleep Latency Test (MSLT) showing both of the following:
      i. Mean sleep latency of 8 minutes or less: AND
      ii. Two (2) or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
   b. The patient has a Multiple Sleep Latency Test (MSLT) showing all of the following:
      i. Mean sleep latency of 8 minutes or less: AND
      ii. One (1) SOREMP: AND
      iii. Additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   c. The patient has 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 3 months

3. 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

Reauthorization:
Documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness
MEDICATION(S)
COLESEVELAM HCL, WELCHOL

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

EXCLUSION CRITERIA
Triglyceride level greater than 500 mg/dL

REQUIRED MEDICAL INFORMATION
HbA1c
TG
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: Hyperlipidemia - 3 months up to 12 months: Diabetes - 3 months up to 6 months.
Reauthorization: 12 months.

OTHER CRITERIA
For Primary Hyperlipidemia:
1. Documented intolerance or contraindication to a generic, high-intensity statin (i.e. atorvastatin 80mg or rosuvastatin 40 mg)
   AND
2. Documented trial, intolerance or contraindication to cholestyramine

For Type 2 diabetes
1. Documentation of trial and failure, contraindication or intolerance to metformin therapy, up to a maximum effective dose of 2000 mg/day
   AND
2. Documented trial and failure of a sulfonylurea or pioglitazone therapy OR contraindications exist to both
of these therapies that precludes trial of a sulfonylurea (e.g., known hypersensitivity reactions to components of product) OR pioglitazone (e.g., Class III or IV heart failure).

AND

3. A documented hemoglobin A1c (HbA1c), obtained within the last six months, that is greater than or equal to 7% and less than or equal to 10%.

Criteria for evaluation of effective response:
Reauthorization requires that the HbA1c remains less than or equal to 9%
MEDICATION(S)
XERMELO

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
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 year

OTHER CRITERIA
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
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)
MEDICATION(S)
XIAFLEX

COVERED USES
Dupuytren’s contracture only, subject to criteria below. Use for Peyronie’s disease is considered a penial procedure that is cosmetic in nature and not covered. Please see Medical Policy No. 193 “Cosmetic and Reconstructive Procedures” and Medical Policy No. 441 “Cosmetic and Reconstructive Procedures (Medicare)”

For Medicaid: Peyronie’s disease is considered “below the line”. Therefore, coverage is dependent on whether the condition adversely affects, or is secondary 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
Treatment of Peyronie’s 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
N/A

COVERAGE DURATION
For Dupuytren’s contracture: Authorization will be approved for 3 months for a maximum of two (2) treatment courses.

OTHER CRITERIA
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
**MEDICATION(S)**
Xifaxan®

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

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

**AGE RESTRICTION**
N/A

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

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

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

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

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

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

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

QUANTITY LIMIT:
200-mg and 550-mg tablets: 3 tablets per day
**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**
Initial authorization will be for six months. Reauthorization will be for one year.

**OTHER CRITERIA**
N/A
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

MEDICATION(S)
XYREM

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Full nocturnal polysomnogram and a multiple sleep latency test (for diagnosis of narcolepsy).

For initiation of treatment, a prior authorization form and relevance 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 a sleep specialist or neurologist

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for one year subject to effective response criteria

OTHER CRITERIA
1. For narcolepsy without cataplexy:
   a. Confirmed diagnosis of narcolepsy:
      i. Full nocturnal polysomnogram and a multiple sleep latency test showing mean onset to sleep less than 10 minutes
      ii. No other polysomnographic reasons to explain sleepiness
   b. Documented trial, failure, intolerance or contraindication to two of the following treatments:
      i. Modafinil
      ii. Armodafinil
      iii. Stimulants (amphetamine or methylphenidate)
   OR
2. For narcolepsy with cataplexy
a. Documented trial, failure, intolerance, or contraindication to modafinil or armodafinil.

Ongoing approval will require documentation that Xyrem® treatment has been effective

QUANTITY LIMIT:
Xyrem® is limited to 9 grams per day, which is 540 mL/30 days.
There is no evidence of additional benefit achieved with Xyrem® doses over 9 grams per day.
MEDICATION(S)
ZINPLAVA

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

EXCLUSION CRITERIA
Patients with existing heart failure

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 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.

OTHER CRITERIA
All of the following criteria must be met for Clostridium difficile infection (CDI):
1. Must be used in combination with standard-of-care antibiotics for treatment (e.g., oral vancomycin, fidaxomicin, metronidazole) AND
2. One of the following:
   a. At least three episodes of mild to moderate CDI that have not responded to six to eight weeks of treatment with standard-of-care antibiotics, including an oral vancomycin taper
   b. Have had at least two episodes of severe CDI that required them to be admitted to the hospital

Reauthorization requires:
1. Previous dose was at least six (6) months ago AND
2. Patient must have had documented benefit from previous infusion, defined as reduction in frequency of recurrences of CDI from baseline
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
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 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
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
   a. For patients with 3 copies of SMN2, documentation of clinical symptoms of disease is required
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 1:50
4. Documentation of baseline tests for liver function, platelet count, and troponin-I
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)

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