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.
**MEDICATION(S)**
ABSTRAL, 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, 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**
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 or older

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

**COVERAGE DURATION**
Initial authorization for six months and reauthorization for one year.
OTHER CRITERIA
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 (such as morphine, hydromorphone, oxymorphone which are all available in both oral and parenteral formulations).
   AND
3. Pain is not controlled with long-acting opioid analgesics.
   AND
4. 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:
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.
**ACIPHEX SPRINKLE/DELIXANT/ESOMEPRAZOLE STRONTIUM CAPSULES/NEXIUM**

**MEDICATION(S)**
ACIPHEX SPRINKLE, DEXILANT, 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**
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

QUANTITY LIMIT: 12 tablets per 28 days

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.
**ALBENZA, EMVERM**

**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):
   - 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.
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 Giarda lamblia: authorization will be approved for 3 days.
For diarrhea caused by Cryptosporidium parvum in patients that are HIV positive: authorization will be approved for 14 days.

OTHER CRITERIA
For diarrhea caused by Cryptosporidium:
1. Confirmed diagnosis of Cryptosporidium parvum
   AND
2. For therapy greater than 3 days, up to 14 days: documentation that patient is HIV positive
For diarrhea caused by Giardia:
1. Confirmed diagnosis of Giardia
   AND
2. Documentation of trial and failure, intolerance, or contraindication to tinidazole

QUANTITY LIMIT:
Nitazoxanide (Alinia®) 500 mg tablets: 6 tablets per day 30 days
Nitazoxanide (Alinia®) 100 mg/ 5 ml suspension: 150 ml per 30 days
MEDICATION(S)
AMITIZA, LINZESS, MOTEGRITY, MOVANTIK, SYMPROIC, TRULANCE

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
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 combination of a stool softener plus a stimulant laxative (e.g. docusate plus senna, docusate sodium plus bisacodyl)
         (3) Routine laxative therapy, with a different mechanism of action than the laxative above (e.g., lactulose, Miralax®)
   b) For irritable bowel syndrome with constipation (IBS-C):
      i) Documentation of abdominal pain or discomfort occurring over at least 6 months with two or more of the following:
         (1) Pain/discomfort relieved with defecation
         (2) Onset associated with a change in stool frequency
         (3) Onset associated with a change in stool form
      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
   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 combination of a stool softener plus a stimulant laxative (e.g. docusate plus senna, docusate sodium plus bisacodyl)
         (2) Routine laxative therapy, with a different mechanism of action than the laxative above (e.g. lactulose, Miralax®)
MEDICATION(S)
AMPYRA, DALFAMPRIDINE ER

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
25-foot walk 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 authorization will be for six months and reauthorization will be approved for one year.
OTHER CRITERIA

Initial authorization criteria:
1. Diagnosis of multiple sclerosis
2. Documentation that patient has difficulty walking (e.g. timed 25 foot walk test)
3. Documentation of one of the following
   a. Patient has an expanded disability status scale (EDSS) score less than or equal to 7
   OR
   b. Patient is not restricted to using a wheelchair (if EDSS is not measured)
4. Medication is prescribed by or in consultation with a neurologist

Reauthorization criteria:
1. Documentation that the patient's walking has improved with Ampyra therapy (such as improvement in 25 foot walk test)
   AND
2. Documentation of one of the following
   a. Patient has an expanded disability status scale (EDSS) score less than or equal to 7
   OR
   b. Patient is not restricted to using a wheelchair (if EDSS is not measured)

QUANTITY LIMIT:
60 tablets for 30 days
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, ONMEL, 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, dermatologist or pulmonologist.

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 Candida infections:
   a. Voriconazole may be covered
   b. For itraconazole or 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 only): 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)

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.
MEDICATION(S)
COARTEM, DARAPRIM

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/uL
**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)
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
FEV1, Alpha 1 antitrypsin (AAT) serum concentrations, current body 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
N/A

COVERAGE DURATION
Initial authorization for 6 months. Reauthorization for one year.
OTHER CRITERIA
Documentation of:
1. Serum alpha-1 antitrypsin (AAT) concentrations less than 11 uM/L (approximately 80mg/dL by immunodiffusion or 50 mg/dL by nephelometry) 
AND
2. Clinical evidence of emphysema as evidenced by:
   a. Forced expiratory volume per one second (FEV1) less than 80% of predicted volume 
      AND
   b. Forced expiratory volume in one second/forced vital capacity (FEV1/FVC) less than 70% 
      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 (0.5gm for Aralast®) within 10% of calculated dose.
MEDICATION(S)
ARANESP, EPOGEN, PROCRIT, RETACRIT

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

EXCLUSION CRITERIA
Patients with uncontrolled hypertension. Darbepoetin alfa or epoetin alfa is not indicated for treating patients with 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 will be for 2 months. Reauthorizations will be for 1 month.
OTHER CRITERIA
1. All diagnoses with the exception of 2f, preoperative use in anemic patients scheduled for elective hip or knee surgery, must have 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, AND
2. Must meet all of the listed criteria below for each specific diagnosis:
   a. Treatment of Anemia in Chronic Renal Failure (CRF)
      i. Aranesp®/Epogen®/Procrit®/Retacrit® may be covered
   b. Treatment of anemia secondary to myelosuppressive chemotherapy in cancer and related neoplastic conditions
      i. There is at least two months of chemotherapy planned post-initiation
         ii. Chemotherapy is not curative in nature (e.g., treatment is for palliative correction of anemia)
         iii. May only be used up to 8 weeks following the final dose of myelosuppressive chemotherapy (subject to audit)
   c. Treatment of Anemia in Myelodysplastic Syndrome (MDS)
      i. Must have documented endogenous serum erythropoietin levels less than 500 mIU/ml
   d. Anemia associated with zidovudine-treated HIV-infection patients:
      i. Coverage is for epoetin only (Procrit®, Epogen®, Retacrit®)
      ii. Documented endogenous serum erythropoietin level is less than or equal to 500 mIU/ml
      iii. Zidovudine dose is less than or equal to 4200mg/week
   e. Anemia associated with the treatment of specific chronic diseases with agents known to cause anemia (rheumatoid arthritis, regional enteritis (or Crohn’s Disease), and ulcerative colitis):
      i. Coverage is for epoetin only (Procrit®, Epogen®, Retacrit®)
      ii. Treatment may not be continued beyond 8 weeks after therapy with agent known to cause anemia is complete
   f. Preoperative use in anemic patients scheduled for elective noncardiac and nonvascular surgery (e.g., hip/knee surgery)
      i. Coverage is for epoetin only (Procrit®, Epogen®, Retacrit®)
      ii. All of the following must be met:
         1. Member has preoperative anemia with pretreatment HGB between 10 and 13 g/dL
         2. The surgery has a high-risk for perioperative blood loss (e.g., expected to lose more than 2 units of blood)
         3. Patient is unwilling to donate autologous blood pre-operatively.
Reauthorization:
1. Documentation of continued medical necessity (e.g., ongoing chronic renal failure)
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)
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) 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)
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 3.5gm/day)
2. Severe active Central Nervous System Lupus
3. Current use of other biologic immunomodulator
4. Current use of IV cyclophosphamide

REQUIRED MEDICAL INFORMATION
Antinuclear antibody (ANA), anti-dsDNA.
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 weight.

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 6 months.
OTHER CRITERIA
All of the following must be met:
1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) by a rheumatologist
   AND
2. Documentation that patient is auto-antibody positive, defined as either:
   a. Antinuclear antibody (ANA) positive defined as:
      i. Titer greater than or equal to 1:80 by immunofluorescence assay (IFA)
      OR
   b. Anti-double-stranded DNA (anti-dsDNA) positive (concentration greater than or equal to 30 IU/ml)
   AND
3. Documentation that patient requires daily use of oral corticosteroids unless contraindicated or not tolerated
   AND
4. Documented trial and failure of, contraindication to, or intolerance to an adequate treatment course with at least two of the following:
   a. Azathioprine
   b. Methotrexate
   c. Mycophenolate moefitil
   d. Hydroxychloroquine
   e. Chloroquine
   f. Cyclophosphamide

Reauthorization:
1. Documentation of response to Benlysta®
   AND
2. Documentation that oral corticosteroid use is stable or decreased

QUANTITY LIMIT:
Belimumab subcutaneous solution: 4 mL/28 days
Belimumab intravenous powder for solution (subject to audit): 10 mg/kg IV 2 weeks for the first 3 doses and every 4 weeks thereafter
   • Belimumab IV is available as 120 mg in a 5-mL single-dose vial and 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)
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. Cervical dystonia in adults
4. Strabismus and blepharospasm associated with dystonia in patients at least 12 years of age
5. Severe axillary hyperhidrosis in adults after documented trial and failure, intolerance or contraindication to topical agents
6. Overactive bladder in adults with:
   a. Symptoms of urge urinary incontinence, urgency, and frequency
   b. Documented trial and failure, intolerance, or contraindication to at least one month of anticholinergic medication (e.g., oxybutynin, tolterodine)
7. Urinary incontinence in adults:
   a. Due to detrusor over activity related to a neurologic condition (e.g., spinal cord injury, multiple sclerosis)
   b. Documented trial and failure, intolerance, or contraindication at least one month of anticholinergic medication (e.g., oxybutynin, tolterodine)
8. Excessive salivation due to advanced Parkinson’s disease
9. Hemifacial spasm

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. 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
**MEDICATION(S)**
CIALIS 5 MG TABLET, RAPAFLO, 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 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)

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

*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
MEDICATION(S)
BRINEURA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Tests to confirm a diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) as required for “other criteria”, baseline CLN2 disease clinical rating scale score.

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

AGE RESTRICTION
May be covered for ages 3-17 years.

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

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

Reauthorization requires documentation of response to therapy, as defined as:
1) No more than a 1-point decline in the Motor Domain of the CLN2 Clinical Rating Scale: AND
2) Motor Domain of the CLN2 Clinical Rating Scale score remains above 0.
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
REFER TO 'OTHER CRITERIA' SECTION FOR DETAILS
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 as a part of an evidence-based treatment program
Reauthorization:
1. Documentation that patient has experienced treatment success (i.e. abstinence from other opioids)
2. Documentation that Probuphine® will be used as a part of an evidence-based treatment program
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 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 as a part of an evidence-based treatment program

Reauthorization:
1. Documentation that patient has experienced treatment success (i.e. abstinence from other opioids)
2. Documentation that patient continues to receive Sublocade® as part of an evidence-based treatment program

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

MEDICATION(S)
AIMOVIG AUTOINJECTOR, AIMOVIG AUTOINJECTOR (2 PACK), AJOVY, EMGALITY PEN, EMGALITY SYRINGE

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 neurologist.

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

Initial authorization:
• Diagnosis of migraine headaches
AND
• Documentation of trial and failure?, intolerance, or contraindication to at least one prophylactic medication from three (3) of the following categories:
o Anticonvulsants (e.g., divalproex, valproate, topiramate)
o Beta-blockers (e.g., metoprolol, propranolol, timolol)
o Antidepressants (e.g., amitriptyline, venlafaxine)
o Botulinum toxin

The requirement for botulinum toxin can be waived for members that have a contraindication to one of the other three categories if the member does not want to use this medication AND
• Documentation that member has not received a botulinum toxin injection in the past three months, or if the patient is currently receiving botulinum toxin, the provider indicates that treatment with botulinum toxin will be discontinued.

Reauthorization:
• Documented reduction in the severity or frequency of headaches.

?An adequate trial and failure is defined as minimal to no improvement after at least three (3) months of therapy.
**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**
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**
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
MEDICATION(S)
KYMRIAH, YESCARTA

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 (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)
• Patient has not previously been treated with gene therapy for their diagnosis
• Repeat administration of CAR-T therapy is considered experimental and investigational because the effectiveness of this approach has not been established

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 allogeneic 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. Patients with Philadelphia chromosome (Ph) positive disease must have a contraindication, intolerance, or have failed two prior lines of tyrosine kinase inhibitor (TKI) therapy (e.g., imatinib): and
4. Member is not eligible for allogeneic stem cell transplant: and
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

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 or more prior treatment regimens: and
3. Prior therapy must have included all of the following unless otherwise not indicated/tolerated:
   a. An anthracycline containing chemotherapy regimen (e.g. doxorubicin), and
   b. Anti-CD20 monoclonal antibody (e.g. rituximab) unless tumor is CD20 negative: and
4. No prior history of treatment with any of the following:
   a. Chimeric antigen receptor therapy or other genetically modified T-cell therapy, or
   b. Allogeneic stem cell transplantation: and
5. Patient is not eligible/failed an autologous stem cell transplant: and
6. No evidence, suspicion, and/or history of primary central nervous system (CNS) lymphoma, seizures, cerebrovascular ischemia/hemorrhage, dementia, brain metastasis, human immunodeficiency virus (HIV), active Hepatitis B or C, active uncontrolled infection and any autoimmune disease requiring immune suppression: and
7. Eastern cooperative oncology group (ECOG) performance status 0-1.
MEDICATION(S)
KALYDECO, ORKAMBI, SYMDEKO

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
• FDA-cleared CF mutation test results
• 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, as specified in reauthorization criteria.

AGE RESTRICTION
N/A

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
For all requests:
1. Documented history of use of the following, unless contraindicated or not appropriate based on age (less than 6 years old) and normal lung function:
   a. Dornase alfa AND
   b. Hypertonic saline AND
   c. Inhaled or oral antibiotics (if appropriate): AND

For ivacaftor (Kalydeco®):
2. Diagnosis of cystic fibrosis with documentation of a cystic fibrosis transmembrane regulator (CFTR) gene mutation that is responsive to ivacaftor (See Appendix 1 and/or package insert): AND

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

For tezacaftor-ivacaftor (Symdeko™):
2. Diagnosis of cystic fibrosis with documentation of a cystic fibrosis transmembrane regulator (CFTR) gene mutation that is responsive to tezacaftor-ivacaftor (See Appendix 2 and/or package insert)

For reauthorization:
Documented response to therapy as defined as one 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. A significant improvement in BMI by 10% from baseline

QUANTITY LIMIT:
Ivacaftor (Kalydeco®): 56 tablets for 28 days or 56 granule packages for 28 days
Lumacaftor-ivacaftor (Orkambi®): 112 tablets for 28 days
Tezacaftor-ivacaftor (Symdeko™): 56 tablets for 28 days
**CHENODAL**

**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 in cerebrotendinous xanthomatosis, must be prescribed by, or in consultation with, a Genetics or Metabolism Specialist.
For use for gallstone dissolution, must be prescribed by a Gastroenterologist.

**COVERAGE DURATION**
Initial authorization will be for six months. Re-authorization will be for one year.

**OTHER CRITERIA**
For use in gallstone dissolution:
1. Documentation that the patient is not a candidate for surgery
   AND
2. Documentation of trial and failure, contraindication or intolerance to ursodiol.
Maximum total duration of therapy authorized for treatment of gallstones will be two years.
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 a 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
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. Reauth may be approved for one year.
OTHER CRITERIA
All of the following must be met:
1. Documentation of one of the following clinical criteria:
   a. Self-limiting, noninflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours, or
   b. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six hours, or
   c. Recurrent laryngeal edema
   AND
2. Documentation of greater than or equal to 2 HAE attacks per month on average for the past 3 months despite removal of triggers (eg. estrogen containing oral contraceptive, angiotensin converting enzyme inhibitors) unless medically necessary
   AND
3. Trial and failure, intolerance or contraindication to long-term prophylaxis with androgen therapy, such as danazol, stanozolol or oxandrolone unless not indicated (eg. pregnancy, lactation, pre-pubescent children),
   AND
4. One of the following:
   a. For HAE Type I and Type II, documentation of at least two (2) complement studies taken at least one month apart with the patient in their basal condition and after the first year of life that show:
      i. C4 is less than 50 percent of the lower limit of normal
      AND
      ii. one of the following:
         a. C1-inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or
         b. C1-INH function is less than 50 percent of the lower limit of normal
   b. For HAE with normal C1-INH or HAE Type III:
      i. Confirmed Factor 12 (FXII) mutation
      OR
      ii. Positive family history for HAE AND attacks lack response with high dose antihistamines or corticosteroids.

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

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

QUANTITY LIMITS:
Cinryze®: 16 vials (500mg each vial) for 28 days
Haegarda®: Weight based 60 units/kg twice weekly for a 28 day supply
Dosing regimens beyond quantity limits will only be approved if evidence-based-rationale is provided.
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.
For chronic heart failure, all of the following must be met:
1. Symptoms consistent with New York Heart Association (NYHA) Class II, III, or IV
2. Left-ventricular ejection fraction of 35% or less
3. Documentation that patient is currently in normal sinus rhythm with resting heart rate of at least 70 bpm
4. On a maximally tolerated dose of a beta-blocker (i.e., carvedilol, metoprolol succinate, bisoprolol) or contraindication to their use
5. Documented trial and failure, contraindication, or intolerance to maximally tolerated dose of an ACE inhibitor (e.g., lisinopril, enalapril) or ARB (e.g., losartan, valsartan)
6. Documentation that the patient has been hospitalized for worsening heart failure in the previous 12 months

For inappropriate sinus tachycardia (IST):
1. Documentation of a sinus heart rate of greater than 100 bpm at rest (with a mean 24-hour heart rate greater than 90 bpm)
2. Documentation that other causes of sinus tachycardia have been ruled out (such as thyroid disease, medications or drugs)
3. Documentation that inappropriate sinus tachycardia is causing significant functional impairment or distress
MEDICATION(S)
CRYSVITA

COVERED USES
Treatment of X-linked hypophosphatemia (XLH) in children and adolescents that are still growing.

EXCLUSION CRITERIA
Treatment of X-linked hypophosphatemia (XLH) in adults and adolescents that are no longer growing.

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. Patient is still growing with documented open epiphyses: and
4. Documentation of radiographic evidence of bone disease including:
   a. Rickets in the wrists and/or knees
   b. Femoral/tibial bowing
   c. Bone fractures
   d. Pseudofractures: and
5. Failure of calcitriol with an oral phosphate agent, unless contraindicated or clinically significant adverse effects are experienced: and
6. 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 that 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 of in number 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
MEDICATION(S)
DALIRESP

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

EXCLUSION CRITERIA
• Asthma without COPD
• Moderate-severe hepatic impairment (Child Pugh B or C)

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 pulmonologist

COVERAGE DURATION
Initial authorization for 3 months, up to 12 months. Reauthorization for 12 months.

OTHER CRITERIA
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)
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.
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
MEDICATION(S)
DIFICID

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 the treatment of individuals 18 years and older

PRESCRIBER RESTRICTION
Dificid® must be prescribed by or in consultation with a physician specializing in infectious disease or gastroenterology.

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

OTHER CRITERIA
Documented trial, failure, intolerance or contraindication to oral vancomycin
**Dihydroergotamine**

**Medication(s)**
D.H.E.45, Dihydroergotamine 1 mg/ml amp, Dihydroergotamine 4 mg/ml spry, Migranal

**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**
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 and re-authorization will be approved for one year.
OTHER CRITERIA
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
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 10^9 /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 10^9 /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 10^9 /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 10^9 /L) or greater

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

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

**COVERED USES**
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 12 months.
OTHER CRITERIA

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 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

Criteria for evaluation of effective response:
Reauthorization requires that the HbA1c remains less than or equal to 9%.
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

**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**
Moderate-to-severe atopic dermatitis: Use in combination with other therapeutic immunomodulators used for the treatment of skin disorders (e.g., Xolair®, Taltz®).

Eosinophilic and corticosteroid dependent asthma: Use in combination with other anti-asthma monoclonal antibodies, such as mepolizumab (Nucala®), benralizumab (Fasenra®), reslizumab (Cinqair®), and omalizumab (Xolair®) for any 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: Must be 12 years of age or older.
Eosinophilic and corticosteroid dependent asthma: Must be 12 years of age or 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).

**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. High-potency topical corticosteroids (e.g., clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least two (2) weeks
   b. Topical calcineurin inhibitor (e.g., tacrolimus ointment) applied twice daily for at least one (1) month
   c. For Medicaid only: Systemic immunomodulatory agents (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate or oral corticosteroids) for at least two (2) months unless contraindicated

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

For eosinophilic asthma:
1. Documentation of eosinophilic asthma by one of the following:
   a. A blood eosinophil count of at least 150 cells/microliter in the past 3 months
   b. A blood eosinophil count of at least 300 cells/microliter in the past 12 months
   c. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids

2. 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)

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

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 two 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

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.
MEDICATION(S)
EGRIFTA

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) of 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).
MEDICATION(S)
ELIDEL, PIMECROLIMUS, 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
Medications are approvable as outlined below:
- Elidel®: 2 years of age and older.
- Tacrolimus ointment 0.03%: 2 years of age and older.
- Tacrolimus ointment 0.1%: 16 years of age and older.

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
4. For Elidel® only: Documented trial, failure, intolerance or contraindication to tacrolimus 0.1% ointment or tacrolimus 0.03% ointment for members less than 16 years of age.
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
5 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. The patient has tried both prednisone daily and prednisone weekend regimen and experienced unmanageable and clinically significant weight gain/obesity or psychiatric/behavioral issues (e.g., abnormal behavior, aggression, irritability)
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)

Note: For weight, gain to be considered a medical complication there must be a greater than 20% absolute increase over baseline in body mass index (BMI) percentile over a year of taking prednisone.

QUANTITY LIMIT:
6 mg tablet: 2 tablets per day,
18 mg tablet: 1 tablet per day.
MEDICATION(S)
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
Enstilar: 18 years of age and older.
Taclonex: 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 400 UNITS VIAL, 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 effectiveness not established in pediatric patients under 8 years of age
• Kanuma®: N/A
• Lumizyme®, Myozyme®: 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 auth will be approved for 6 months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
Documentation of FDA-labeled indication.

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. 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
N/A

REQUIRED MEDICAL INFORMATION
Forced Vital Capacity (FVC), high-resolution computed tomography.

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 pulmonologist.

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

OTHER CRITERIA
Confirmed diagnosis of Idiopathic Pulmonary Fibrosis and presence of a histological pattern associated with usual interstitial pneumonia (UIP) on high-resolution computed tomography or lung biopsy.
**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)
EVZIO

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
Narcan® nasal spray does not require prior authorization, but may be subject to quantity limits

All of the following criteria must be met:
1. One of the following:
   a) Patient is a current heroin/opioid abuser and 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

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
EXONDYS 51 - MEDICAL BENEFIT

MEDICATION(S)
EXONDYS 51

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
Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

NOTE: This indication is approved under accelerated approval based on an increase in dystrophin in skeletal muscle observed in some patients treated with Exondys 51®. A clinical benefit of Exondys 51® has not been established. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials. Eteplirsen (Exondys 51®) will not be covered by Providence Health Plan 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 (Gilenya®)
FENTANYL CITRATE

MEDICATION(S)
ACTIQ, FENTANYL CIT OTFC 1,200 MCG, FENTANYL CIT OTFC 1,600 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 400 MCG, FENTANYL CITRATE OTFC 600 MCG, FENTANYL CITRATE OTFC 800 MCG

COVERED USES
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 16 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
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 two formulary oral or parenteral short-acting narcotic agents.
   AND
3. Pain is not controlled with long-acting narcotic analgesics.

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
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
Approved for age 18 years of age and older

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

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.
MEDICATION(S)
FORTEO

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: 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 total duration of Forteo® and Tymlos® therapy does not exceed 2 years of total therapy duration for any combination of osteoanabolic therapies.
OTHER CRITERIA
For the treatment or prevention of osteoporosis:

1. One of the following criteria:
   a. Documented clinical diagnosis of osteoporosis [defined as a non-traumatic, non-pathologic spinal fracture OR spine, or hip bone mineral density (BMD) T-score less than or equal to -2.5].
   OR
   b. Documented risk of osteoporosis (defined as BMD T-score between -1.0 and -2.5) AND meeting one of two risk assessments
      A. one of the following risk factors:
         i. previous fracture
         ii. history of hip or spine fracture in first degree relative
         iii. low body weight (less than 127 lbs. for women)
         iv. smoking, excess alcohol intake
         v. secondary osteoporosis (e.g. rheumatoid arthritis)
         vi. history of falls
      OR
      B. Fracture Risk Assessment (FRAX) Hip fracture probability greater than or equal to 3% or other major osteoporosis fracture probability greater than or equal to 20%
      OR
   c. One of the following chronic glucocorticosteroid use:
      A. greater than 20 mg/day for longer than 1 month
      B. 5-20 mg/day for longer than 3 months in post-menopausal women not on estrogen
      C. 5-20 mg/day for longer than 3 months AND T-score less than -1.5
      AND
   2. Documentation of trial and failure of bisphosphonate therapy or contraindication/intolerance to both oral and IV bisphosphonate therapy.
   Failure is defined as a new fracture or worsening bone mineral density while adherent to bisphosphonate therapy
   a. For patients that have gastrointestinal side effects to oral bisphosphonate therapy, documentation of trial and failure of IV bisphosphonate therapy will be required.
   AND
   3. Documentation of trial and failure or contraindication/intolerance to Prolia® (denosumab). Failure is defined as a new fracture or worsening bone mineral density while adherent to Prolia® (denosumab).
   AND
   4. For female patients only: 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
   a. Total duration of treatment with Tymlos® (abaloparatide) has not exceeded two years.
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
**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 109/L, neutrophils less than 1 x 109/L
   d. Hypertriglyceridemia (fasting triglycerides greater than 3 mmol/L or equal or greater than 265 mg/dL) and/or hypofibrinogenemia (equal or less than 1.5 g/L)
   e. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
   f. Low or absent NK-cell activity
   g. Ferritin equal or greater than 500 mcg/L
   h. Soluble CD 25 equal or greater than 2400 U/mL

2. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy (corticosteroids, methotrexate, cyclosporine A, etoposide, anti-thymocyte globulin) based on one of the following criteria:
   a. Having not responded or not achieved a satisfactory response
   b. Having not maintained a satisfactory response to conventional HLH therapy
   c. Intolerance to conventional HLH treatments

3. Patient is a candidate for stem cell transplant and emapalumab is being used as part of the induction or maintenance phase for stem cell transplant and will be discontinued at the initiation of conditioning for stem cell transplant

4. Dosing is in accordance with the United States Food and Drug Administration approved labeling

5. Documentation that patient currently has no active infection (e.g. mycobacteria and Histoplasma Capsulatum)

Reauthorization Criteria:

1. Patient continues to be a candidate for stem cell transplant

2. Documentation of disease improvement such as:
   a. Complete response defined as normalization of all HLH abnormalities (i.e. no fever, no splenomegaly, neutrophils greater than 1x109/L, platelets greater than 100x109/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)**
BIVIGAM, CARIMUNE NF NANOFILTERED, CUTAQUIG, CUVITRU, FLEBOGAMMA DIF, 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

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

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

Indication-Specific Requirements:

Primary immune deficiency disorders such as agammaglobulinemia, hypogammaglobulinemia (i.e., common variable immunodeficiency), Hyper-IgM (i.e., X-linked or autosomal recessive hypogammaglobulinemia), Wiskott-Aldrich syndrome or Secondary immunodeficiency due to drugs/biologics agents, underlying disease or other causes:

1. Documentation of significant recurrent infections
   AND
2. One of the following
   a. Laboratory evidence of immunoglobulin deficiency:
      i. Agammaglobulinemia (total IgG less than 200 mg/dL)
      ii. Persistent hypogammaglobulinemia (total IgG less than 400 mg/dl, or at least two standard deviations below normal, on at least two occasions)
   OR
   b. Deficiency in producing antibodies in response to vaccination

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

Prevention of infections in patients with B-cell chronic lymphocytic leukemia (CLL):
1. Documented endogenous IgG less than 500 mg/dL
   OR
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 or if platelet count less than 10,000 and minor purpura
   b. 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 with acute bleeding or high-risk of bleeding and member had trial, failure or contraindication to a corticosteroid
   b. To defer or avoid splenectomy
   c. Planned surgery, dental extractions, or other procedures likely to cause blood loss (platelet count goal is generally greater than 50,000)

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 18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a Gastroenterologist

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

OTHER CRITERIA
Gattex treatment is indicated for adult members when the following criteria are met:
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. 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

QUANTITY LIMITS: Weight based dosing (0.05 mg/kg daily) should be rounded to the smallest number of 5mg-kits, when within 10% of calculated dose
MEDICATION(S)
Giazo

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 male patients 18 years and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization for 8 weeks

OTHER CRITERIA
Documentation of trial and failure of or contraindication to generic balsalazide and a second oral formulary agent indicated for the treatment of ulcerative colitis (e.g. mesalamine, Delzicol, Asacol HD).

The initial approval of Giazo® will allow for an 8-week treatment course. Further approval for Giazo® requires medical rationale why standard maintenance therapy with generic balsalazide or other medication for ulcerative colitis is not appropriate.
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)
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: authorization/reauthorization will be approved for up to 6 months (Total of 12 months for Lupron®/Lupaneta® Pack, 6 months for Synarel®/Zoladex®)
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
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.

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 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 initiation of central precocious puberty treatment
Note, a one-time dose may be approved for diagnostic purposes
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 of the following:
   a. Pubertal response to a GnRH stimulation test
   b. Pubertal level of basal luteinizing hormone levels
   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® and Supprelin®

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 AND

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 90-400 MG TABLET, LEDIPASVIR-SOFOSBUVIR, MAVYRET, OLYSIO, SOFOSBUVIR-VELPASVIR, SOVALDI, TECHNIVIE, VIEKIRA PAK, VIEKIRA XR, VOSEVI, ZEPATIER

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

**EXCLUSION CRITERIA**
All regimens containing a protease inhibitor (grazoprevir elbasvir, glecaprevir, simeprevir, paritaprevir, or voxilaprevir as found in Zepatier®, Mavyret®, Olysio®, Viekira®, Technivie® or Vosevi®) are not covered in patients with moderate to severe hepatic impairment (Child-Pugh B and C).

**REQUIRED MEDICAL INFORMATION**
For initiation of treatment, a prior authorization form and relevant chart notes documenting specific HCV genotype, recent liver fibrosis score, Child-Pugh score if patient has cirrhosis, baseline HCV RNA count, 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.
1. Documentation of confirmed diagnosis of chronic hepatitis C (HCV) 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
   b. Baseline HCV RNA level in past 6 months
   c. 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.
   d. 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
   e. 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.
   f. Cirrhosis status as determined by clinical, radiologic or laboratory evidence (ascites, portal hypertension, hepatic encephalopathy, hepatocellular carcinoma, esophageal varices) 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 Zepatier® in genotype 1a, or Daklinza® in genotype 3, NS5A resistance testing is required to detect any potential resistant variant.
   Note: 1) Zepatier® with ribavirin for 16 weeks is recommended in patients with genotype 1a CHC who have baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93. 2) In clinical trial, patients with genotype 3 CHC who have baseline NS5A Y93H polymorphism had a reduced SVR12 rate (53%) when treated with Daklinza® and sofosbuvir for 12 weeks.

QUANTITY LIMIT:
28 day-supply per dispense
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. Reauth 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
MEDICATION(S)
HORIZANT

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

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For 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.
HUMAN GROWTH HORMONE FOR PEDIATRICS

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.

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

1. Documented evidence of open epiphyses
   AND
2. For growth hormone request other than Omnitrope®, documentation that the patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to Omnitrope®
   AND
3. Meet criteria listed below for each specific diagnosis:
   A. Growth Hormone Deficiency (GHD)
      1) Evidence of short stature/growth failure by one of the following:
         i. Height standard deviation score (SDS) of more than 3 SD below the mean for chronological age/sex OR
         ii. 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) OR
         iii. 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

   2) Documented biochemical GHD by one of the following:
      i. 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, OR
      ii. One GH stim test below 10 ng/ml in children with defined CNS pathology, history of irradiation, or genetic conditions associated with GHD OR
      iii. One GH stim test level less than 15 ng/ml and insulin-like growth factor (IGF)-1 and IGFBP-3 levels below normal for bone age/sex OR
      iv. Evidence of multiple pituitary hormone deficiencies (at least one other deficient hormone including LH, FSH, TSH, and ACTH).
   B. Prader-Willi Syndrome (PWS)
      1) Documented confirmation of diagnosis through genetic testing
   C. Turner’s Syndrome (TS)
      1) Diagnosis confirmed by genetic testing
      AND
   2) Evidence of short stature/growth failure meeting one of the criteria above (A.1.i-iii)
   D. Noonan Syndrome
      1) 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
2) Evidence of short stature/growth failure meeting one of the criteria above (A.1.i-iii)
E. Chronic Renal Insufficiency
1) Other causes of growth failure have been ruled out and nutritional status has been optimized

AND

2) Evidence of short stature/growth failure meeting one of the criteria above (A.1.i-iii)

Authorization will be withdrawn after transplantation.
F. Small for Gestational Age (SGA)
1) Birth weight and/or length at least three SDs below the mean for gestational age

AND

2) Failure to reach catch-up growth by two years of age, defined as height at least two SDs below the mean for age/sex

Reauthorization criteria:
1. Evidence of growth velocity (GV) of greater than 2.5 cm/year

AND

2. Evidence of open epiphyses
MEDICATION(S)
CINQAIR, FASENRA, NUCALA

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

EXCLUSION CRITERIA
When used in combination with other anti-asthma monoclonal antibodies, such as omalizumab (Xolair®) or dupilumab (Dupixent®) (for asthma or any indication).

REQUIRED MEDICAL INFORMATION
For asthma: Absolute Eosinophil Count, and Asthma Control Test (ACT) or Asthma Control Questionnaire (ACQ) 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
Nucala®: Approved for 12 years of age or older
Cinqair®: Approved for 18 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
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 at least 150 cells/microliter in the past 3 months
   b. A blood eosinophil count of at least 300 cells/microliter in the past 12 months
   c. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids
2. 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)
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

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)
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

REQUIRED MEDICAL INFORMATION
Plasma IGF-1 activity, blood glucose, plasma insulin, 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)
BRAVELLE, 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, secondary amenorrhea, and cryptorchidism subject to criteria below.

EXCLUSION CRITERIA
The treatment of infertility if a benefit exclusion for the Oregon Health Plan and is excluded from coverage. Medications used in all forms and variations of In-Vitro Fertilization (IVF) including: Gamete Intrafallopian transfer (GIFT), Zygote intrafallopian transfer (ZIFT), and Intracytoplasmic Sperm Injection (ICSI) are excluded from coverage, except for those groups with the benefit covering 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 IVF.

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

COVERAGE DURATION
Authorization will be approved for one year.
OTHER CRITERIA
For treatment of infertility:
Must meet the following definition of infertility, which is the failure to achieve a successful pregnancy after:
a. 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination in women less than 35 years of age OR
b. 6 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination in women 35 years and older

1.Must meet criteria for specific cause of infertility, as follows:
a. For females with secondary amenorrhea, progesterone preparations may be covered if the following criteria are met:
i. Patient has experienced an absence of menses for more than 3 months (or 6 months in patients with a history of irregular menses), AND
ii. Anatomic or pathologic causes (e.g. pregnancy, thyroid disease, celiac disease, type 1 diabetes mellitus) have been ruled out
b. For females with polycystic ovary syndrome (PCOS), gonadotropins may be covered if the following criteria are met:
i. Documented failure of clomiphene or letrozole or intolerance or contraindication to clomiphene and letrozole. Failure is defined as inability to conceive after at least 3 treatment cycles with clomiphene or letrozole: AND
ii. Documentation of concurrent use of metformin, unless there is an intolerance or contraindication to its use.
c. For females with other ovulatory disorders, gonadotropins may be covered if the following criterion is met:
i. Documented failure, intolerance or contraindication to clomiphene. Failure is defined as inability to conceive after at least 3 treatment cycles with clomiphene.
d. For males, requests for chorionic gonadotropin therapy (e.g., Pregnyl®, Novarel®) may be approved with confirmation of hypogonadism, as follows: Low levels of luteinizing hormone (LH) and follicle-stimulating hormone (FSH)
i. Requests for other gonadotropin therapies (i.e., FSH or LH/FSH preparations) may be approved after documentation of failure, intolerance or contraindication to chorionic gonadotropin therapy. Failure is defined as inability to conceive after at least 6 months.
e. For males with sperm defects (e.g., low counts, low motility, morphologic abnormalities), procedural medications may be covered if criterion 1 is met

For maintenance of pregnancy, progesterone formulations may be approved with:
1. Documentation of current pregnancy
OR
2. Documentation that patient has history of prior pregnancy loss

For males with cryptorchidism, chorionic gonadotropin therapy may be approved if the patient is between the ages of 4 and 9 years if there is 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, AVASTIN, AZACITIDINE, AZEDRA DOSIMETRIC, AZEDRA THERAPEUTIC, BAVENCIO, BELEODAQ, BELRAPZO, BENDAMUSTINE HCL, BENDEKA, BESPONSA, BLINCYTO, BORTEZOMIB, CYRAMZA, DACOGEN, DARZALEX, DECITABINE, EMPLICITI, ERBITUX, FASLODEX, FOLOTYN, FULVESTRANT, HALAVEN, HERCEPTIN, HERCEPTIN HYLECTA, IMFINZI, IMLYGIC, ISTODAX, IXEMPRA, JEVTANA, KADCYLA, KANJINTI, KEYTRUDA, KYPROLIS, LARTRUVO, LIBTAYO, LUMOXITI, LUTATHERA, MELPHALAN HCL, MVASI, ONIVYDE, OPDIVO, PERJETA, POLIVY, PORTRAZZA, POTELEGEO, ROMIDEPSIN, SYLATRON, SYLATRON 4-PACK, SYNRIBO, TECENTRIQ, TEMODAR 100 MG VIAL, TEMSIROLIMUS, TORISEL, TREANDA, VECTIBIX, VELCADE, VIDAZA, VYXEOS, XOFIGO, YERVOY, YONDELIS, ZALTRAP

**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.
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.
CURRENT 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
N/A

COVERAGE DURATION
Initial authorization will be approved for up to six months. Reauth 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. Current use of high-intensity statin therapy for at least 3 months, defined as atorvastatin 80 mg daily or rosuvastatin (Crestor®) 40 mg daily, OR
   b. Documented statin intolerance. Statin intolerance is defined as 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.
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
Headache and migraines

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 chronic migraine headache or episodic migraine
   AND
2. Documented trial and failure, intolerance or contraindication to a formulary triptan (e.g. frovatriptan, naratriptan, rizatriptan, sumatriptan, Zomig® nasal spray)

Reauthorization criteria: Documentation of a positive clinical response to the requested therapy (e.g. reduction in headache days or severity).

QUANTITY LIMIT:
15 mg/mL vials or syringes – 4 mL per 28 days
30 mg/mL vials or syringes – 4 mL per 28 days
60 mg/2 mL vials or syringes – 4 mL per 28 days
**MEDICATION(S)**
KEVEYIS

**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
MEDICATION(S)
KRYSTEXXA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For 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
1. Frequent and disabling gout flares (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. If allopurinol is not tolerated or contraindicated, a documented trial, failure, contraindication or intolerance to febuxostat (Uloric®) will be required. AND
3. Documented trial, failure, contraindication or intolerance to probenecid.

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

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
N/A

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 1 month prior to starting therapy is above 6 mg/dL (360 micromol/L) in children less than 12 years of age, or above 15 mg/dL (900 micromol/L) for ages 12 and older.

For reauthorization:
1. Documentation that average blood Phe levels have 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)**
LEMTTRAAD

**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.*
LIDOCAINE PATCH

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
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

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

MEDICATION(S)
ARYMO ER, AVINZA, BELBUCA, BUPRENORPHINE, BUTRANS, EMBEDA, EXALGO, HYDROMORPHONE ER, HYSINGLA ER, MORPHABOND ER, MORPHINE SULFATE ER 120 MG CAP, MORPHINE SULFATE ER 30 MG CAP, MORPHINE SULFATE ER 45 MG CAP, MORPHINE SULFATE ER 60 MG CAP, MORPHINE SULFATE ER 75 MG CAP, MORPHINE SULFATE ER 90 MG CAP, 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 or surgery.

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 for up to one year.
OTHER CRITERIA
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.

CRITERIA:
For Avinza®, Exalgo®, Hysingla® ER, Opana® ER, OxyContin®, Xartemis®, Xtampza® and Zohydro®:
OR
2. All of the following:
   a. Trial and failure of two other narcotic analgesic agents including one long-acting morphine sulfate product, unless contraindicated
   AND
   b. Documentation of persistent pain that is severe enough to require daily, around-the-clock, opioid treatment for at least the previous 90 days

For Embeda®, Arymo®, and Morphabond®:
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
   AND
2. Documentation of persistent pain that is severe enough to require daily, around-the-clock, opioid treatment for at least the previous 90 days

For Belbuca® and Butrans®:
OR
2. All of the following:
   a. Trial and failure of two other narcotic analgesic agents including one long-acting morphine sulfate product or long-acting tramadol product, unless contraindicated
   AND
   b. Documentation of persistent pain that is severe enough to require daily, around-the-clock, opioid treatment for at least the previous 90 days
   AND
   C. For Belbuca®: trial and failure of Butrans®

QUANTITY LIMIT:
Arymo® 15 mg and 30 mg tablets: 90 tablets per 30 days
Arymo® 60 mg tablets: 60 tablets per 30 days
Avinza® all strengths: 30 capsules per 30 days
Belbuca® all strengths: 60 films per 30 days
Butrans® all strengths: 4 patches per 28 days
Exalgo®: 30 tablets per 30 days
Hysingla® ER: 30 tablets per 30 days
Morphabond® ER 15 mg, 30 mg and 60 mg tablets: 60 tablets per 30 days
Morphabond® ER 100 mg tablets: 30 tablets per 30 days
Opana® ER 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg: 60 tablets per 30 days
Opana® ER 30 mg, 40 mg: 30 tablets per 30 days
OxyContin® 10 mg, 15 mg, 20 mg, 30 mg and 40 mg tablets: 60 tablets per 30 days
OxyContin® 60 mg and 80 mg tablets: 30 tablets per 30 days
Xartemis®: limit of 120 tablets per 30 days
Xtampza® ER: 60 capsules per 30 days
Zohydro® ER: 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) for further details
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 μm thickness shown on optical coherence tomography: and
   b. The member has remaining light perception in the intended treatment eye
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.
MEDICATION(S)
24 HOUR NASAL ALLERGY, 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
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
Acute sinusitis comorbidity: Authorization will be approved for one (1) month
All other indications: Initial authorization and reauthorization will be approved for up to one year.
OTHER CRITERIA
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 mediation 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
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.
MEDICATION(S)
BUPHENYL, 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: AND
2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis (e.g., high-quality peer reviewed literature, guidelines, other clinical information)

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

MEDICATION(S)
ATOVAQUONE, MEPRON

COVERED USES
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/reauth for 1 year. For Babesiosis: Initial/reauth for 10 days for 1 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: 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
N/A

COVERAGE DURATION
Initial approval and renewal for 1 year.
OTHER CRITERIA
For the treatment or prevention of osteoporosis:
1. Documentation of trial and failure of bisphosphonate therapy or contraindication/intolerance to both oral and IV bisphosphonate therapy. Failure is defined as a new fracture or worsening bone mineral density while adherent to bisphosphonate therapy.
a. For patients that have gastrointestinal side effects to oral bisphosphonate therapy, documentation of trial and failure of IV bisphosphonate therapy will be required.

AND
2. One of the following criteria:
a. Documented clinical diagnosis of osteoporosis [defined as a non-traumatic, non-pathologic spinal fracture OR spine, or hip bone mineral density (BMD) T-score less than or equal to -2.5].
OR
b. Documented risk of osteoporosis (defined as BMD T-score between -1.0 and -2.5) AND meeting one of two risk assessments

A. one of the following risk factors:
   i. previous fracture
   ii. history of hip or spine fracture in first degree relative
   iii. low body weight (less than 127 lbs. for women)
   iv. smoking, excess alcohol intake
   v. secondary osteoporosis (e.g. rheumatoid arthritis)
   vi. history of falls
OR
B. Fracture Risk Assessment (FRAX) Hip fracture probability greater than or equal to 3% or other major osteoporosis fracture probability greater than or equal to 20%
OR
c. One of the following chronic glucocorticosteroid use:
   A. greater than 20 mg/day for longer than 1 month
   B. 5-20 mg/day for longer than 3 months in post-menopausal women not on estrogen
   C. 5-20 mg/day for longer than 3 months AND T-score less than -1.5

For Treatment of Paget’s Disease:
1. Documentation of trial and failure of bisphosphonate therapy or contraindication/intolerance to both oral and IV bisphosphonate therapy.
**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 renal failure:
• 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

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:
• Documented hemodialysis for at least 8 weeks
• Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least 8 weeks prior to initiation of therapy
• 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 renal failure)
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
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, ADHANSIA XR, ADOXA 150 MG CAPSULE, ADZENYS ER, ADZENYS XR-ODT, AMLODIPINE-VALSARTAN-HCTZ, AMPHETAMINE SULFATE, AMRIX, APLENZIN ER 348 MG TABLET, ASTPEEDRO, AZELASTINE 0.15% NASAL SPRAY, BETAMETHASONE VALER 0.12% FOAM, BIDIL, BUPROPION HCL XL 450 MG TABLET, BUTALB-ACETAMIN-CAFF 50-300-40, 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, CONZIP, CUPRIMINE, CYCLOBENZAPRINE HCL ER, DAXBIA, DERMASORB HC, DERMASORB TA, DESLORATADINE 2.5 MG ODT, DESLORATADINE 5 MG ODT, DESONATE, DESOXIMETASONE 0.25% SPRAY, DIFFERIN 0.1% LOTION, DORYX, DORYX MPC, DOXYCYCLINE 50 MG TABLET, DOXYCYCLINE HYC DR 100 MG TAB, DOXYCYCLINE HYC DR 150 MG TAB, DOXYCYCLINE HYC DR 200 MG TAB, DOXYCYCLINE HYC DR 50 MG TAB, DOXYCYCLINE HYC DR 75 MG TAB, DOXYCYCLINE HYC DR 80 MG TAB, DOXYCYCLINE HYCLATE 150 MG TAB, DOXYCYCLINE HYCLATE 75 MG TAB, DOXYCYCLINE IR-DR, DOXYCYCLINE MONO 150 MG CAP, DOXYCYCLINE MONO 75 MG CAPSULE, DUEXIS, DUOBRII, DURLAZA, DUTOPROL, DYMISTA, ECOZA, EDLUAR, EVEKEO, EVEKEO ODT, EXFORGE HCT, EZALLOR SPRINKLE, FENOBIBRATE 150 MG CAPSULE, FENOBIBRATE 50 MG CAPSULE, FIORICET, FLO-PRED, FLUVOXAMINE MALEATE ER, FORFIVO XL, FORTAMET, FOSAMAX PLUS D, GLUMETZA, GOCOVRI, GONITRO, GRALISE, HALOBETASOL PROP 0.05% FOAM, HYDROCORT BUTO 0.1% LIPID CRM, HYDROCORT BUTF 0.1% LIPO CREAM, HYDROCORTISONE BUTYR 0.1% LOTN, IMPOYZ, JORNAY PM, KENALOG, KITABIS PAK, LEXETTE, LIPOFEN, LOCOID 0.1% LOTION, LOCOID LIPOCREAM, LORZONE, LUXIQ, LYRICA CR, METFORMIN ER GASTRIC, METFORMIN ER OSMOTIC, METOCLOPRAMIDE HCL ODT, METOPROLOL SUCCINATE ER-HCTZ, METOZOLV ODT, 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, NORITATE, OKEBO 75 MG CAPSULE, OLEPTRO ER, OLMESARTAN-AMLODIPINE-HCTZ, OMEPPI, OMEPRAZOLE-SODIUM BICARBONATE, ONEXTON, ONZETRA XSAIL, ORacea, ORBIVAN, PENICILLAMINE 250 MG CAPSULE, PENNSAID, PHRENILIN FORTE 50-300-40 MG, PRAMIPEXOLE ER, PRESTALIA, QMIIZ ODT, RAYOS, REQUIP XL 12 MG TABLET, REQUIP XL 6 MG TABLET, REQUIP XL 8 MG TABLET, RETIN-A MICRO, RETIN-A MICRO PUMP 0.04% GEL, RETIN-A MICRO PUMP 0.08% GEL, RETIN-A MICRO PUMP 0.1% GEL, ROPINIROLE HCL ER 12 MG TABLET, ROPINIROLE HCL ER 6 MG TABLET, ROPINIROLE HCL ER 8 MG TABLET, RYVENT, SERNIVO, SEYSARA 60 MG TABLET, SOLIQUA 100-33, SOLODYN, SOLOXIDE, SORILUX, SPRITAM, SUMATRIPTAN SUCC-NAPROXEN SOD, SUMAVEL DOSEPRO, TARGADOX, TELMISARTAN-AMLODIPINE, TIVORBEX, TOBRAMYCIN PAK 300 MG/5 ML, TOLSURA, TOPICORT 0.05% SPRAY, TRAMADOL HCL ER 100 MG CAPSULE, TRAMADOL HCL ER 150 MG CAPSULE, TRAMADOL HCL ER 200 MG CAPSULE, TRAMADOL HCL ER 300 MG CAPSULE, TRETIN-X 0.05% COMBO PACK, TRETIN-X 0.075% CREAM, TRETIN-X 0.1% COMBO PACK, TRETINOIN MICROSPHERE, TREXIMET, TRIAMCINOLONE 0.147 MG/G SPRAY, TRIBENZOR, TUXARIN ER, TWYNSTA, ULTRAVATE 0.05% LOTION, ULTRAVATE X, VELTIN, VERDESO, VIVLODEX, WHYTEDERM TDPAK,
WHYTEDEERM TRILASIL PAK, XHANCE, XIMINO, XOLEGEL, XULTOPHY 100-3.6, ZEGERID, ZEGERID OTC, ZEMBRACE SYMTOUCH, ZIANA, ZIPSOR, ZMAX, ZOLPIMIST, ZORVOLEX, ZTLIDO, ZUPLENZ

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).
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. Reauth approved for up to 6 months.
OTHER CRITERIA
Must meet all of the following:
1. A diagnosis of chronic immune thrombocytopenia (ITP)
   AND
2. Patient is at risk for bleeding with a platelet count of less than 30 x 10^9/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
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
Not recommended for use in children younger than 18 years of age.

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
1. Trial and failure of tramadol
   AND
2. Documentation of trial and failure of a formulary short-acting opioid analgesic (such as oxycodone)
NUCYNTA ER

MEDICATION(S)
NUCYNTA ER

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

EXCLUSION CRITERIA
As needed (prn) use.

REQUIRED MEDICAL INFORMATION
For 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 1 year

OTHER CRITERIA
For Chronic Pain:
1. Documentation of trial and failure, contraindication, or intolerance to tramadol ER and extended release morphine sulfate.
   AND
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 gabapentin and one tricyclic antidepressant (TCA), selective serotonin reuptake inhibitor (SSRI) or serotonin–norepinephrine reuptake inhibitor (SNRI)

QUANTITY LIMIT:
Limit to 60 tablets per 30 days.
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)
NUPLAZID

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
-Mini-mental status exam (MMSE) score or Saint Louis University Mental Status (SLUMS) exam 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
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a specialist in psychiatry, neurology, or geriatrics.

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.
OTHER CRITERIA
1. Diagnosis of Parkinson’s disease with hallucinations and/or delusions causing clinically significant distress, with delirium ruled out
   AND
2. Mini-mental status exam (MMSE) score greater than or equal to 21 or Saint Louis University Mental Status (SLUMS) exam score greater than or equal to 16, to indicate that patients can self-report symptoms
   AND
3. Documented trial, failure, intolerance to clozapine or quetiapine OR contraindication to both clozapine and quetiapine

Reauthorization criteria:
Documented reduction in frequency and/or severity of hallucinations and/or delusions.

QUANTITY LIMIT:
Nuplazid 10 mg tablet: 1 tablet/day
Nuplazid 17 mg tablet: 2 tablets/day
Nuplazid 34 mg capsule: 1 capsule/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 Cirrhosis 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
**OCTREOTIDE/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

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Baseline cardiac status including ECG, renal function. 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
MEDICATION(S)
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
   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

   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)
MEDICATION(S)
ABIRATERONE ACETATE, AFINITOR, AFINITOR DISPERZ, ALECENSA, ALKERAN 2 MG TABLET, ALUNBRIG, BALVERSA, BEXAROTENE, BOSULIF, BRAFTOVI, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLEADA, ERLOTINIB HCL, FARYDAK, GILOTRIF, GLEEVEC, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA, INLYTA, INREBIC, 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, TAGRISSO, TALZENNA, TARCEVA, TARGRETIN, TASIGNA, TEMODAR 100 MG CAPSULE, TEMODAR 140 MG CAPSULE, TEMODAR 180 MG CAPSULE, TEMODAR 20 MG CAPSULE, TEMODAR 250 MG CAPSULE, TEMODAR 5 MG CAPSULE, TEMOZOLOMIDE, TIBSOVO, TRETINOIN 10 MG CAPSULE, TURALIO, TYKERB, VANDETANIB, VENCELEXTA, VENCELEXTA STARTING PACK, VERZENIO, VESANOID, VITRAKVI, VIZIMPRO, VOTRIENT, XALKORI, XOSPATA, XPOVIO, XTANDI, YONSA, ZEZULA, ZELBORAF, ZOLINZA, ZYDELIK, 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
For Turalio® only: preexisting hepatic impairment (e.g. serum transaminases, total bilirubin, or direct bilirubin greater than upper limit of normal, active liver or biliary tract 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.
For Erleada®, Prostate Specific Antigen Doubling time will be required.

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 Inrebic®, patient has tried and failed, a contraindication, or an intolerance to Jakafi® (ruxolitinib)?
3. For Turalio®:
   a. Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT), also known as pigmented villonodular synovitis
   AND
   b. Documentation of symptomatic diffuse articular forms that is in recurrence or in rapid progression where total resection may induce severe morbidity

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
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
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 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
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:
Limited to 300 tablets per 30 days
Opioid doses more 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
**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

MEDICATION(S)
OPANA 10 MG TABLET, OPANA 5 MG TABLET, 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
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 up to one year.
OTHER CRITERIA
Documentation of trial and failure, contraindication or intolerance to:
1) 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)
   AND
2) immediate release morphine sulfate
   AND
3) immediate release oxycodone

QUANTITY LIMITS:
• Oxymorphone 5 mg: limited to 240 tablets per 30 days
• Oxymorphone 10 mg: limited to 120 tablets per 30 days

Quantity Limits are based on 120 mg morphine equivalents per day dosing
See Maximum Allowable Opioid Dose in Non-Malignant Chronic Pain policy (ORPTCANA31)
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 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

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
MEDICATION(S)
AMINOSYN, AMINOSYN II, AMINOSYN M, AMINOSYN 7%-ELECTROLYTE SOL, AMINOSYN-PF, AMINOSYN-RF, FREAMINE HBC, HEPATAMINE, INTRALIPID, NUTRILIPID, PROCALAMINE, PROSOL, SMOFLIPID

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-authorization 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.
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 rosuvastatin (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 xanthomas 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)**

**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**
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 and reauthorization will be approved for 1 month

OTHER CRITERIA
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
MEDICATION(S)
LOKELMA, VELTASSA

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

EXCLUSION CRITERIA
Dialysis

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 letemovir is being requested, rationale for not using oral formulation must be provided (e.g. patient is unable to swallow)
PROCYSBI

MEDICATION(S)
PROCYSBI

COVERED USES
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.
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
MEDICATION(S)
PROLIA

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. 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 medical necessity and effectiveness of medication.
OTHER CRITERIA
For osteoporosis, must meet all criteria below:
1. Documentation of failure of bisphosphonate therapy (e.g. new fracture or worsening bone mineral density) OR contraindication/intolerance to both oral and IV bisphosphonate therapy.
   a. For patients that have gastrointestinal side effects to oral bisphosphonate therapy, documentation of trial and failure of IV bisphosphonate therapy will be required.
   AND
2. One of the following criteria:
   A. Documented clinical diagnosis of osteoporosis (defined as a non-traumatic, non-pathologic spinal fracture OR spine or hip bone mineral density (BMD) T-score less than or equal to -2.5)
   OR
   B. Documented risk of osteoporosis (defined as BMD T-score between -1.0 and -2.5) AND meeting one of the following two risk assessments:
      1. One of the following risk factors:
         a. previous fracture
         b. history of hip or spine fracture in first degree relative
         c. low body weight (less than 127 lbs for women)
         d. smoking, excess alcohol intake
         e. secondary osteoporosis (e.g. rheumatoid arthritis)
         f. history of falls
      2. Fracture Risk Assessment (FRAX®) Hip fracture probability greater than or equal to 3% or other major osteoporosis fracture probability greater than or equal to 20%
      OR
   C. One of the following chronic glucocorticosteroid use:
      a. greater than 20 mg/day of prednisone or equivalent for longer than 1 month
      b. 5-20 mg/day of prednisone or equivalent for longer than 3 months in post-menopausal women not on estrogen
      c. 5-20 mg/day of prednisone or equivalent for longer than 3 months AND T-score less than -1.5

For men at high risk of fracture receiving androgen deprivation therapy (ADT) for non-metastatic prostate cancer:
1. Documentation of FRAX® hip fracture probability of greater than or equal to 3% or other major osteoporosis fracture probability greater than or equal to 20%. Note that ADT should be considered “secondary osteoporosis” when using the FRAX® algorithm
   AND
2. Documentation of trial and failure, contraindication, or intolerance to alendronate or zoledronic acid
   a. For patients that have gastrointestinal side effects to alendronate, documentation of trial and failure of zoledronic acid therapy will be required.

For women at high risk of fracture receiving adjuvant aromatase inhibitor therapy for breast cancer:
1. If premenopausal, documentation of failure of bisphosphonate therapy (e.g. new fracture or worsening bone mineral density) or contraindication/intolerance to both oral and IV bisphosphonate therapy.
   a. For patients that have gastrointestinal side effects to oral bisphosphonate therapy, documentation of trial and failure of IV bisphosphonate therapy will be required.
2. If postmenopausal (natural or induced), denosumab may be approved
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. Reauth approved for 6 months.

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

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

For Reauthorization for ITP or severe aplastic anemia:
Platelet levels demonstrating response to therapy as well as documentation that eltrombopag continues to be required to maintain a platelet count of at least 50 x 10 to the 9th power per liter.
MEDICATION(S)
PROVENGEB

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, AMBRISSENTAN, 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
Pulmonary arterial hypertension

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of single agent 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 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
The following criteria must be documented:
1. Catheterization-proven diagnosis of Pulmonary Arterial Hypertension (PAH) 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) less than or equal to 15 mmHg
   AND
2. Patient has documented World Health Organization (WHO) Group 1 classification (PAH) and a WHO/New York Heart Association (NYHA) functional class status as outlined below:
   A. Flolan®, Veletri®, and Ventavis: Class III or IV
   B. Tyvaso®: at least Class III
   C. All other therapies: at least Class II
   AND
3. For tadalafil tablet (Adcirca®) and sildenafil citrate oral suspension or infusion (Revatio®):
   Documentation of trial and failure, intolerance, or contraindication to generic sildenafil citrate tablets (Revatio®)
   Reauthorization: Documentation of response to therapy

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

COVERAGE DURATION
Initial authorization will be approved for four (4) months
Reauthorization will be approved for six (6) months
OTHER CRITERIA
1. Diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by one 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 dAMP, 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

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 and autoimmune hemolytic anemia (AIHA) subject to criteria.

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, rheumatologist, neurologist (in the case of RRMS), 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
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 of the following targeted immune modulators: Enbrel®, Humira®, Remicade®, Simponi® 50mg 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, unless medical rationale is provided to support monotherapy.

Reauthorization requires documentation of adequate response to therapy.

For Vasculitis (including Granulomatosis with Polyangiitis (GPA, formerly known as Wegener’s Granulomatosis), Microscopic Polyangiitis (MPA), and polyarteritis nodosa):
1. Documentation that rituximab will be given in combination with glucocorticoids.
   AND
2. One of the following:
   a. Documentation of severe disease (e.g., critical organ system involvement)
   OR
   b. Documentation of trial and failure, intolerance, or contraindication to systemic immunosuppressant therapy with cyclophosphamide or methotrexate

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 preferred disease modifying agents 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
SABRIL

MEDICATION(S)
SABRIL, VIGABATRIN, VIGADRONE

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For 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
SECOND AND THIRD GENERATION ANTIHISTAMINES

**MEDICATION(S)**
24HR ALLERGY RELIEF, ALAVERT, KRO ALL DAY ALLERGY 10 MG SFGL, ALL DAY ALLERGY-D, ALLEGRA ALLERGY, ALLEGRA-D 12 HOUR, ALLEGRA-D 24 HOUR, ALLER-EASE, ALLER-FEX, ALLER-TEC D, ALLERCLEAR D-12HR, ALLERCLEAR D-24HR, ALLERGY COMPLETE-D, ALLERGY D-12, ALLERGY RELIEF 10 MG ODT, ALLERGY RELIEF 180 MG TABLET, ALLERGY RLF(CETRZN) 10 MG SFGL, CVS ALLERGY RELIEF 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 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-24HR, ALLERGY RELIEF-D, ALLERGY RELIEF-D12, ALLERGY RELIEF-NASAL DECONGEST, ALLERGY+CONGESTION RELIEF-D, ALLERGY-CONGESTION 12HR, ALLERGY-CONGESTION ER, ALLERGY-CONGESTION RELIEF, ALLERGY-CONGESTION RELIEF 12HR, ALLERGY-CONGESTION RELIEF-D, CETIRI-D, CETIRIZINE HCL 10 MG CHEW TAB, CETIRIZINE HCL 5 MG CHEW TAB, CETIRIZINE HCL 5 MG/5 ML SOLN, CETIRIZINE-PSEUDOEPHEDRINE ER, CHILDREN'S ALLEGRA ALLERGY, CVS CHILD ALLERGY 10 MG CHEW TB, CVS CHILD ALLERGY RLF 30 MG/5, CHILD CETIRIZINE 10 MG CHEW TB, CHILD CETIRIZINE 5 MG CHEW TAB, CHILDREN'S WAL-FEX, CHILD'S WAL-ZYR 10 MG CHEW TAB, CHILDREN'S ZYRTEC ALLERGY, CLARITIN 10 MG LIQUI-GEL CAP, CLARITIN 10 MG REDITABS, CLARITIN 5 MG REDITABS, CLARITIN-D 24 HOUR, FEXOFENADINE HCL 180 MG TABLET, FEXOFENADINE HCL 30 MG/5 ML, FEXOFENADINE HCL 60 MG TABLET, HM FEXOFENADINE HCL 180 MG TAB, HM FEXOFENADINE HCL 60 MG TAB, QC FEXOFENADINE HCL 180 MG TAB, SM FEXOFENADINE HCL 180 MG TAB, SM FEXOFENADINE HCL 60 MG TAB, FEXOFENADINE-PSE ER, LEVOCETIRIZINE 2.5 MG/5 ML SOL, LEVOCETIRIZINE 5 MG TABLET, LORATA-D, LORATA-DINE D, LORATADINE 10 MG ODT, LORATADINE 10 MG SOFTGEL, 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 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**
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
Please see specific product information for age restrictions.

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
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.
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

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
N/A

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)
**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**
1. Documentation that the patient has persistent, moderate-to-severe symptoms of disease (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)

Reauthorization requires documentation of response to therapy, as defined as normalization of insulin-like growth factor (IGF)-1 and reduction of symptoms
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.
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
Prescribed by an Hematologist/Oncologist

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):
   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

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.
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**
N/A

**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 medical geneticist, or bone and mineral specialist.

**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 confirmed by ALL of the following criteria:
1. Patient younger than 18 at onset of disease
2. One of the following:
   a. Confirmation of 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
3. One or more of the following HPP-related findings:
   a. Radiographic evidence of HPP (e.g., skeletal abnormalities)
   b. History or presence of non-traumatic fracture or delayed fracture healing
   c. Nephrocalcinosis or history of elevated serum calcium
   d. Functional craniosynostosis (early fusion of skull bones which may sometimes result in increased cranial pressure)
   e. Respiratory compromise or rachitic chest deformity
   f. Vitamin B6-responsive seizures
   g. Failure to thrive

Reauthorization:
Documentation of response to therapy with either improvement in respiratory status, skeletal manifestations or growth (in pediatric patients).

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
Initial authorization and reauthorization will be approved for one year.
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 at least two conventional formulary allergy medications (e.g. levocetirizine, fluticasone nasal spray)
   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 aeroallergen:
   • Grastek: Timothy grass or cross-reactive grass
   • Oralair: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass
   • Ragwitek: Short Ragweed
   • Odactra: house dust mite
   AND
5. No other allergens are being treated concurrently with subcutaneous immunotherapy

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

For coverage by OHP Medicaid members:
Sublingual immunotherapy treatment requires prior authorization for OHP 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 OHP members include:

1. Patient must have a co-morbid diagnosis of asthma
   OR
2. Co-morbid diagnosis of COPD III or IV or obstructive chronic bronchitis
   OR
3. One of the following co-morbid conditions that are above the line:
   a) Chronic inflammation of the orbit
   b) Chronic sinusitis
   c) Sleep apnea
   OR
4. The member is routinely using oxygen therapy
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, 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
1. Patients that require the use of drugs known to alter gastrointestinal motility (i.e. GI anticholinergics, metoclopramide). 2) 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 an endocrinologist 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
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

Criteria for evaluation of effective response:
Reauthorization requires that the 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)**
CLOQUIQUE, 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®).
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
TESTOSTERONE REPLACEMENT THERAPY (TRT)

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

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

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

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication
OTHER CRITERIA
For patients established on testosterone replacement therapy:
1. Documented trial and failure of generic topical testosterone 1%. Failure is defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms

For initiation of testosterone replacement therapy, all of the following criteria must be met:
1. Documentation of trial and failure, contraindication or intolerance to generic topical testosterone 1%. Failure is defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms: AND
2. One of the following:
   a. Diagnosis of gender dysphoria or gender identity disorder
   OR
   b. Diagnosis of primary or secondary (hypogonadatropic) hypogonadism: AND confirmatory laboratory values, as outlined below, taken before 11 am, or within 3 hours of waking for shift-workers, on different days without acute illness/stress, according to the local laboratory’s lower limit of normal (if available) or levels according to the listed values below:
      i. At least two (2) serum total testosterone levels less than 264 ng/dL (9.2 nmol/L) OR
      ii. At least two (2) free testosterone levels less than 2 ng/dL (20 pg/mL) OR
      iii. At least one (1) serum total testosterone level less than 264 ng/dL (9.2 nmol/L) AND one (1) free testosterone levels less than 2 ng/dL (20 pg/mL). Serum total testosterone level and free testosterone level must be taken on different days.
MEDICATION(S)
ACTEMRA, ACTEMRA ACTPEN, CIMZIA, COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE, ENBREL, ENBREL MINI, ENBREL SURECLICK, ENTYVIO, HUMIRA, HUMIRA PEDIATRIC CROHN'S, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS, HUMIRA PEN PSOR-UVEITS-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN'S, HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PSOR-UV-ADOL HS, INFLECTRA, KEVZARA, KINERET, OLUMIANT, ORENCIA, ORENCIA CLICKJECT, OTEZLA, REMICADE, RENFLEXIS, SILIQ, SIMPONI, SIMPONI ARIA, SKYRIZI (2 SYRINGES) KIT, STELARA, TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE, TALTZ SYRINGE (2 PACK), TALTZ SYRINGE (3 PACK), 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.

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
      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)
      ii. 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 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

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 1 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 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

3. Documented trial, failure, intolerance or contraindication to penicillamine (Depen®)

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

MEDICATION(S)
JYNARQUE, SAMSCA

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 out 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
TYMLOS

MEDICATION(S)
TYMLOS

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: 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 total duration of Forteo® and/or Tymlos® does not exceed 2 years of total therapy duration for any combination of osteoanabolic therapies.
OTHER CRITERIA
For the treatment or prevention of osteoporosis in postmenopausal women:

1. One of the following criteria:
   a. Documented clinical diagnosis of osteoporosis [defined as a non-traumatic, non-pathologic spinal fracture OR spine, or hip bone mineral density (BMD) T-score less than or equal to -2.5].
   OR
   b. Documented risk of osteoporosis (defined as BMD T-score between -1.0 and -2.5) AND meeting one of two risk assessments
      A. One of the following risk factors:
          i. previous fracture
          ii. history of hip or spine fracture in first degree relative
          iii. low body weight (less than 127 lbs. for women)
          iv. smoking, excess alcohol intake
          v. secondary osteoporosis (e.g. rheumatoid arthritis)
          vi. history of falls
      OR
      B. Fracture Risk Assessment (FRAX) Hip fracture probability greater than or equal to 3% or other major osteoporosis fracture probability greater than or equal to 20%
      OR
   c. One of the following chronic glucocorticosteroid use:
      A. greater than 20 mg/day for longer than 1 month
      B. 5-20 mg/day for longer than 3 months in post-menopausal women not on estrogen
      C. 5-20 mg/day for longer than 3 months AND T-score less than -1.5
      AND
   2. Documentation of trial and failure of bisphosphonate therapy or contraindication/intolerance to both oral and IV bisphosphonate therapy.
      Failure is defined as a new fracture or worsening bone mineral density while adherent to bisphosphonate therapy
      a. For patients that have gastrointestinal side effects to oral bisphosphonate therapy, documentation of trial and failure of IV bisphosphonate therapy will be required.
      AND
   3. Documentation of trial and failure or contraindication/intolerance to Prolia® (denosumab).
      Failure is defined as a new fracture or worsening bone mineral density while adherent to Prolia® (denosumab).
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-? 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
All the following criteria must be met:
• Trial and failure of or contraindication to a topical AND an oral formulary agent indicated for the treatment of ulcerative colitis (e.g. mesalamine enema or suppositories, Delzicol, Asacol HD).

The initial approval of Uceris® will allow for an 8-week treatment course. Further approval for Uceris® requires medical rationale why standard maintenance therapy with generic budesonide or other medication for ulcerative colitis 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
Approved for 18 years of age and older

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a 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
For initial authorization for Paroxysmal Nocturnal Hemoglobinuria (PNH), 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.

For reauthorization for PNH:
Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms
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. 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
1. Trial (defined as 2 months of therapy), failure, or contraindication to a formulary agent to treat very high triglycerides such as fenofibrate.
   AND
2. A triglyceride level within the past 6 months that is greater than 500 mg/dL.
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)
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
Initial authorization and reauthorization will be approved for up to one year.

OTHER CRITERIA
1) Documented trial and failure of atorvastatin 80 mg and rosuvastatin 40 mg daily, and 2) 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)**  
COLESEVELAM HCL, WELCHOL

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

**EXCLUSION CRITERIA**  
Monotherapy for the treatment of type 2 diabetes. Triglyceride level greater than 500 mg/dL.

**REQUIRED MEDICAL INFORMATION**  
1) HbA1c. 2) 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 cholestryramine

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%

EXCLUSION CRITERIA:
Monotherapy for the treatment of type 2 diabetes.
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.
**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**
N/A

**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 octreotide therapy (e.g., octreotide LAR (Sandostatin LAR®), lanreotide (Somatuline®) for at least three (3) months
3. Documentation of failure of both of the following agents for breakthrough symptoms: loperamide and short-acting octreotide (Sandostatin®). Failure is defined as continuing to experience four (4) or more bowel movements per day despite daily use of these agents
4. Documentation that long-acting octreotide therapy will be used in combination with the requested medication

Reauthorization will require documentation of reduction in frequency of bowel movements by at least 30%
MEDICATION(S)
XGEVA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For prevention of skeletal-related events in patients with bone metastases from solid tumors: documentation confirming bone metastasis. 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 prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors: documented trial and failure of, intolerance to, or contraindication to zoledronic acid or pamidronate therapy.
MEDIATION(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
Traveler’s diarrhea: One-time 3-day treatment course (Quantity of 9 of the 200 mg tablets)
IBS-D: 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).
Hepatic Encephalopathy: 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 (HE) (550 mg tablets): Documentation of trial and failure, contraindication or intolerance to lactulose

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

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

QUANTITY LIMIT:
200 mg and 550 mg: 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**
Use in combination with other anti-asthma monoclonal antibodies, such as mepolizumab (Nucala®), reslizumab (Cinqair®), and dupilumab (Dupixent®) for any indication.

**REQUIRED MEDICAL INFORMATION**
For asthma: IgE, Asthma Control Test (ACT) or Asthma Control Questionnaire (ACQ) score

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

**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**
Uticaria: 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
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 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).
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
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 infectious disease specialist or gastroenterology specialist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for a one-time 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 oral 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 antibiotics, including a 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
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
Use may be approved for individuals 12 years of age and older.

PRESCRIBER RESTRICTION
N/A

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

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