Medicare Advantage Plans

2020 Prior Authorization (PA)

AdventHealth Advantage Plans is administered by Health First Health Plans. Health First Health Plans is an HMO plan with a Medicare Contract. Enrollment in Health First Health Plans depends on contract renewal.

Y0089_MINFO7901AH_C(10/19)
Drugs
acitretin

Exclusion Criteria
Severely impaired liver or kidney function. Chronic abnormally elevated blood lipid values. Concomitant use of methotrexate or tetracyclines. Pregnancy. Females of child-bearing potential who intend to become pregnant during therapy or at any time for at least 3 years after discontinuing therapy. Females of child-bearing potential who will not use reliable contraception while undergoing treatment and for at least 3 years following discontinuation. Females of child-bearing potential who drink alcohol during treatment or for two months after cessation of therapy.

Required Medical Information
Diagnosis of severe psoriasis.

Age Restriction
18 years of age or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
ACTIMMUNE

Exclusion Criteria
Hypersensitivity to interferon gamma, E. coli derived proteins, or any component of the formulation.

Required Medical Information
Diagnosis of chronic granulomatous disease or severe malignant osteoporosis.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria
Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Pregnancy. Concomitant administration with nitrates or nitric oxide donors (such as amyl nitrate) in any form. Concomitant administration with phosphodiesterase inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline).

Required Medical Information

Age Restriction
18 years of age or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
For renewal, medication was effective (i.e. improved 6 minute walk distance, oxygen saturation, etc.)

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
AFINITOR, AFINITOR DISPERZ, everolimus (antineoplastic)

Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Advanced metastatic renal cell carcinoma and patient has failed therapy (disease progressed) with Sutent or Nexavar (Afinitor or everolimus), or B) Progressive pancreatic, nonfunctional GI or lung neuroendocrine tumors (NET) that are unresectable, locally advanced or metastatic (Afinitor or everolimus), or C) Renal angiomyolipoma with tuberous sclerosis complex (TSC) and patient does not require immediate surgery (Afinitor or everolimus), or D) Advanced hormone receptor-positive, HER2-negative breast cancer and patient is a postmenopausal woman and patient has failed treatment with Femara or Arimidex and the medication will be used in combination with Aromasin (Afinitor or everolimus), or E) Subependymal giant cell astrocytoma (SEGA) associated with TSC that requires therapeutic intervention but is not a candidate for curative surgical resection (Afinitor or Afinitor Disperz only), or F) TSC-associated partial-onset seizures (Afinitor Disperz only).

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
ALECENSA (alectinib)

Drugs
ALECENSA

Exclusion Criteria

Required Medical Information
Documented diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
alosetron

Exclusion Criteria
Initial therapy for Irritable Bowel Syndrome (IBS) in the male gender.

Required Medical Information
Diagnosis of irritable bowel syndrome with diarrhea and failed at least TWO alternatives from different classes such as antidiarrheals (e.g. loperamide), antispasmodics (e.g. dicyclomine). Reauthorization for Irritable Bowel Syndrome (IBS): 1. Recurrence of diarrhea predominant IBS, AND 2. documentation of positive clinical response while on alosetron.

Age Restriction
18 years of age or older

Prescriber Restriction
Prescriber must be specially trained gastrointestinal physician

Coverage Duration
IBS Initial Therapy: 12 weeks Reauthorization: 6 months

Other Criteria
Initial Therapy for Irritable Bowel Syndrome (IBS): 1. Failure to both: a. An antispasmodic (e.g. dicyclomine) AND b. An anti-diarrhea agent (e.g. loperamide, diphenoxylate-atropine).

Indications
All FDA-approved Indications.

Off Label Uses
Alunbrig

Drugs
ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG, ALUNBRIG ORAL TABLETS, DOSE PACK

Exclusion Criteria

Required Medical Information
diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.

Age Restriction

Prescriber Restriction
Oncologist

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
dalfampridine

Exclusion Criteria
History of seizure. Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute). Patient currently using any other forms of 4-aminopyridine.

Required Medical Information
Diagnosis of multiple sclerosis AND patient is ambulatory (able to walk at least 25 feet) AND patient has walking impairment.

Age Restriction

Prescriber Restriction
Neurologist

Coverage Duration
Initial: 3 months. Renewal: through end of benefit year.

Other Criteria
For renewal, documentation that walking speed has improved from baseline must be provided.

Indications
All FDA-approved Indications.

Off Label Uses
ANADROL-50 (Oxymetholone)

Drugs
ANADROL-50

Exclusion Criteria
1. Carcinoma of the prostate or breast in male patients. 2. Carcinoma of the breast in females with hypercalcemia, androgenic anabolic steroids may stimulate osteolytic resorption of bones. 3. Pregnancy 4. Nephrosis or the nephrotic phase of nephritis. 5. Severe hepatic dysfunction.

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Use with 5HT3-antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alocetron).

Required Medical Information

Age Restriction

Prescriber Restriction
Neurologist for initial prescription

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

**Required Medical Information**
Diagnosis of partial-onset seizures and treatment failure of at least two other formulary medications used in the treatment of partial-onset seizures.

**Age Restriction**

**Prescriber Restriction**
Neurologist

**Coverage Duration**
Through end of benefit year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria

**Required Medical Information**
Diagnosis of cryopyrin-associated period syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS).

**Age Restriction**
12 years of age and older

**Prescriber Restriction**
Prescribed by or in consultation with or recommendation of, an immunologist, allergist, dermatologist, rheumatologist, neurologist, or other medical specialist.

**Coverage Duration**
Through end of benefit year

**Other Criteria**
Approve doses based on FDA labeling.

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria
Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

Required Medical Information
Diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting MS or progressive-relapsing MS, or secondary-progressive MS) OR patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Austedo

Drugs
AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG

Exclusion Criteria

Required Medical Information
Documented diagnosis of 1) chorea associated with Huntington’s disease OR 2)tardive dyskinesia

Age Restriction
18 years of age or older

Prescriber Restriction

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
AVONEX

Drugs
AVONEX INTRAMUSCULAR PEN INJECTOR KIT, AVONEX INTRAMUSCULAR SYRINGE KIT

Exclusion Criteria
Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

Required Medical Information
Diagnosis of relapsing form of multiple sclerosis OR diagnosis of first clinical episode and MRI features consistent with multiple sclerosis

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Ayvakit (avapritinib)

Drugs
AYVAKIT

Exclusion Criteria

Required Medical Information
documentation of unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation.

Age Restriction

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Balversa (Erdafitinib)

Drugs
BALVERSA

Exclusion Criteria

Required Medical Information
Documented diagnosis of locally advanced or metastatic urothelial carcinoma AND member has susceptible FGFR3 or FGFR2 genetic alteration as detected by an FDA-approved companion diagnostic AND disease has progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Age Restriction
18 years or older

Prescriber Restriction

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
**BANZEL**

**Drugs**
BANZEL ORAL SUSPENSION, BANZEL ORAL TABLET 200 MG, 400 MG

**Exclusion Criteria**
Banzel is not covered for members with the diagnosis of Familial Short QT syndrome

**Required Medical Information**
Diagnosis of Lennox-Gastaut syndrome. Documentation of previous therapies and that the current medication regimen is inadequate to control disease.

**Age Restriction**
Must be 1 years of age or older

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year

**Other Criteria**
Patient must be refractory to at least 2 of the following: Felbamate (Felbatol), Lamotrigine (Lamictal), Topiramate (Topamax), Valproic acid (Depakene), Divalproex sodium (Depakote)

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs

BENLYSTA SUBCUTANEOUS

Exclusion Criteria
Benlysta (belimumab) therapy is not considered medically necessary for members with the following concomitant conditions: severe active lupus nephritis, severe active central nervous system lupus, or in combination with other biologic products (examples include Humira, Enbrel, Remicade, Rituexan, Stelara, Cimzia, Kineret, Amevive, Ocrevus, Simponi, Actemra), including B-cell targeted therapies or intravenous (IV) cyclophosphamide.

Required Medical Information
This agent may be considered medically necessary when the following criteria are met: Systemic Lupus Erythematosus (SLE). The member must have a diagnosis of active systemic lupus erythematosus (SLE). The member must be autoantibody positive in the absence of any drugs for SLE defined as: ANA titer greater than or equal 1:80 or anti-dsDNA level greater than or equal 30 I/mL. The member must be utilizing Benlysta (belimumab) in combination with standard treatment regimens for SLE which may include: corticosteroids (ex: prednisone), hydroxychloroquine, azathioprine.

Age Restriction
18 years of age and older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Benznidazole

Drugs
benznidazole

Exclusion Criteria
Patients who have used disulfiram within two weeks of initiation of benznidazole

Required Medical Information
Documentation of a consultation with an infectious disease specialist. Reviewer will verify patient claim history to confirm that patient has not used disulfiram within two weeks prior to benznidazole initiation

Age Restriction

Prescriber Restriction

Coverage Duration
60 days

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

Required Medical Information
Diagnosis of relapsing form of multiple sclerosis OR diagnosis of first clinical episode and MRI features consistent with multiple sclerosis.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses

BETASERON SUBCUTANEOUS KIT
Drugs
**BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG**

**Exclusion Criteria**
Coverage is not provided in those that have the BCR-ABL1 T315I mutation and use of Bosulif in combination with other kinase inhibitors (for example sorafenib, sunitinib, etc.)

**Required Medical Information**
Diagnosis of Philadelphia chromosome-positive chronic myelogenous leukemia.

**Age Restriction**
18 years of age and older

**Prescriber Restriction**
Hematologist/Oncologist

**Coverage Duration**
3 Months

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Braftovi (Encorafenib)

Drugs
BRAFTOVI ORAL CAPSULE 75 MG

Exclusion Criteria

Required Medical Information
Documentation of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test and the medication will be used in combination with binimetinib.

Age Restriction

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Brand Antipsychotics

Drugs
ABILIFY MAINTENA, ARISTADA INTRAMUSCULAR SUSPENSION, EXTENDED REL SYRING 441 MG/1.6 ML, CAPLYTA, GEODON INTRAMUSCULAR, REXULTI, ZYPREXA RELPREVV INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION 210 MG

Exclusion Criteria

Required Medical Information
Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosed with partial-onset seizures and treatment failure of at least two other formulary medications used in the treatment of partial onset seizures.

Age Restriction

Prescriber Restriction
Neurologist

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
**Exclusion Criteria**

**Required Medical Information**
Documentation of mantle cell lymphoma (MCL) in patients who have received at least one prior therapy.

**Age Restriction**

**Prescriber Restriction**
Oncology

**Coverage Duration**
3 Months

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
*sodium phenylbutyrate oral tablet*

Exclusion Criteria

**Required Medical Information**
Diagnosis of urea cycle disorder (UCD) was confirmed by enzymatic, biochemical or genetic testing. Requested drug will be used for chronic management of UCD.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**
Three months. Renewable with documentation of benefit.

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
BUTALBITAL CONTAINING PRODUCTS

Drugs

Exclusion Criteria

Required Medical Information
Medical documentation of FDA-approved indication, AND trial and failure or contraindication to one preferred alternatives. Preferred alternatives include: NSAIDs such as ibuprofen.

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
CABLIVI INJECTION KIT

Exclusion Criteria

Required Medical Information
Documented diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) AND must be used in combination with plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or rituximab)

Age Restriction
18 years of age or older

Prescriber Restriction
hematologist

Coverage Duration
30 days

Other Criteria
Reauthorization: additional therapy up to a maximum 28 additional days will be approved with documentation of remaining signs of persistent underlying disease (such as suppressed ADAMTS13 activity levels)

Indications
All FDA-approved Indications.

Off Label Uses
CABOMETYX (cabozantinib)

Drugs
CABOMETYX ORAL TABLET 20 MG, 40 MG, 60 MG

Exclusion Criteria

Required Medical Information
Diagnosis of advanced renal cell carcinoma (RCC) or hepatocellular carcinoma in patients who have been previously treated with sorafenib.

Age Restriction

Prescriber Restriction

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
AIMOVIG AUTOINJECTOR, AJOVY SYRINGE

Exclusion Criteria

Required Medical Information
Clinical documentation of migraines and member has tried and failed two formulary alternatives for migraine prophylaxis with two different mechanism of action such as Beta Blockers (metoprolol and propranolol), Antidepressants (amitriptyline and venlafaxine), Anticonvulsants (valproate and topiramate), Calcium Channel Blockers (verapamil and diltiazem), and Angiotensin-converting enzyme inhibitors/ angiotensin II receptor blockers (losartan and lisinopril).

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documented diagnosis of mantle cell lymphoma (MCL) who have received at least one prior therapy.

Age Restriction

Prescriber Restriction
Oncologist or hematologist

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
CANCIDAS, caspofungin

Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Empirical therapy for presumed fungal infections in febrile, neutropenic patients, or B) Treatment of candidemia and other Candida infections (intraabdominal abscesses, peritonitis and pleural space infections), or C) Treatment of esophageal candidiasis, or D) Treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies (amphotericin B, itraconazole).

Age Restriction
3 months of age or older

Prescriber Restriction

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
CAPRELSA

Drugs
CAPRELSA ORAL TABLET 100 MG, 300 MG

Exclusion Criteria
Congenital long QT syndrome

Required Medical Information
Diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease.

Age Restriction
18 years or older

Prescriber Restriction
Oncologist or endocrinologist

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of NAGS deficiency was confirmed by enzymatic or genetic testing.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of cystic fibrosis AND patient has evidence of P. aeruginosa in the lungs

Age Restriction
7 years of age and older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
For renewal, Patient is benefiting from treatment (i.e. improvement in lung function [FEV1], decreased number of pulmonary exacerbations)

Indications
All FDA-approved Indications.

Off Label Uses
**Exclusion Criteria**

**Required Medical Information**
Diagnostic laboratory testing for HAE has been performed (eg, C4, C1 inhibitor functional, and C1 inhibitor antigenic protein levels). For patients with HAE with C1 inhibitor deficiency, C1 inhibitor antigenic protein level and/or C1 inhibitor functional level is below the lower limit of normal as defined by the laboratory performing the test. For patients with HAE with normal C1 inhibitor, other causes of angioedema have been ruled out (eg, drug-induced) and EITHER 1) Patient tested positive for the F12 gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of antihistamine (eg, levocetirizine) for at least one month.

**Age Restriction**

**Prescriber Restriction**
Must be prescribed by Dermatologist, Hematologist, or Allergist/Immunologist

**Coverage Duration**
3 months

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
CLOVIQUE

Exclusion Criteria
Not recommended in cystinuria or rheumatoid arthritis. Not indicated for biliary cirrhosis.

Required Medical Information
For use in patients with diagnosis of Wilson disease who are intolerant to penicillamine.

Age Restriction
Geriatric patients: Use with caution. Initiate at lower end of the dosing range. Pediatric dosage: Children and adolescents: Oral: Initial: 20 mg/kg/day (round dose to the nearest 250 mg) in 2 to 3 divided doses. Maximum initial daily dose: 1,000 mg/day. Titrate dose based on clinical response and free serum copper (non-ceruloplasmin bound copper) concentrations and/or 24-hour urinary copper excretion. Usual maintenance dose: 900 to 1,500 mg/day in 2 to 3 divided doses.

Prescriber Restriction
Coverage Duration
Through end of benefit year.

Other Criteria
Indications
All FDA-approved Indications.

Off Label Uses
Drugs
COMETRIQ ORAL CAPSULE 100 MG/DAY (80 MG X 1-20 MG X 1), 140 MG/DAY (80 MG X 1-20 MG X 3), 60 MG/DAY (20 MG X 3/DAY)

Exclusion Criteria
Gastrointestinal perforation. Fistula. Severe hemorrhage.

Required Medical Information
Diagnosis of progressive metastatic, medullary thyroid cancer.

Age Restriction
18 years or older

Prescriber Restriction
Oncologist/Hematologist

Coverage Duration
3 Months

Other Criteria
Indications
All FDA-approved Indications.

Off Label Uses
Drugs
*glatiramer subcutaneous syringe 20 mg/mL, 40 mg/mL, GLATOPA SUBCUTANEOUS SYRINGE 20 MG/ML, 40 MG/ML*

Exclusion Criteria
Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

Required Medical Information
Diagnosis of relapsing-remitting multiple sclerosis OR diagnosis of first clinical episode with MRI features consistent with multiple sclerosis.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
COPIKTRA

Exclusion Criteria

Required Medical Information
Documentation of the following: A) relapsed or refractory CLL or SLL after at least two prior therapies OR B) relapsed or refractory FL after at least two prior systemic therapies.

Age Restriction

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

**Required Medical Information**
Must be clinically diagnosed with A) stable, symptomatic chronic heart failure in adults with left ventricular ejection fraction less than or equal to 35% supported by documentation from the patient's medical records, AND have sinus rhythm with resting heart rate greater than or equal to 70 beats per minute, AND be on maximally tolerated doses of beta blockers unless contraindicated, AND be on optimal therapy with standard treatment of ACEI or ARB unless intolerant or contraindicated, AND be on optimal therapy with standard treatment of an aldosterone antagonist unless intolerant or contraindicated, AND documentation of trial and failure of Entresto OR B) stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older AND have sinus rhythm with an elevated heart rate.

**Age Restriction**

**Prescriber Restriction**
Cardiologist

**Coverage Duration**
Through end of benefit year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Cosentyx

Drugs
COSENTYX (2 SYRINGES), COSENTYX PEN (2 PENS)

Exclusion Criteria

Required Medical Information
Documented trial and failure of preferred TNF inhibitors (Enbrel and Humira) AND patient is free of any clinically important active infections.

Age Restriction

Prescriber Restriction

Coverage Duration
Initial Authorization will be for 3 months. Reauthorization will be for 1 year.

Other Criteria
Criteria and quantity restrictions will be applied consistent with current FDA-approved doses and indications.

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
dorzolamide-timolol (PF) ophthalmic (eye) dropperette

Exclusion Criteria

Required Medical Information
Clinical documentation of trial of 1 ophthalmic beta blocker AND rationale for requiring preservative free formulation.

Age Restriction

Prescriber Restriction
Ophthalmologist

Coverage Duration
Through the end of the benefit year.

Other Criteria
Ocular hypertension, In patients who are insufficiently responsive to beta-blockers1 drop dorzolamide 2%/timolol 0.5% topically to affected eye(s) twice dailyOpen-angle glaucoma, In patients who are insufficiently responsive to beta-blockers1 drop dorzolamide 2%/timolol 0.5% topically to affected eye(s) twice daily

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
COTELLIC

Exclusion Criteria

**Required Medical Information**
Documented unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year.

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria

**Required Medical Information**
Diagnosis of type 2 diabetes mellitus

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
CYSTAGON

Exclusion Criteria

Required Medical Information
Diagnosis of nephropathic cystinosis confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing.

Age Restriction

Prescriber Restriction

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

**Required Medical Information**
Diagnosis of cystinosis was confirmed by the presence of increased cystine concentration in leukocytes or by DNA testing. The patient has corneal cystine crystal accumulation.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year.

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
DAURISMO ORAL TABLET 100 MG, 25 MG

Exclusion Criteria

Required Medical Information
Documentation that the medication will be used in combination with low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML), and the patient is A) 75 years of age or older OR B) has comorbidities that preclude use of intensive induction chemotherapy.

Age Restriction

Prescriber Restriction
oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
DEMSER

Exclusion Criteria

Required Medical Information
Statement of diagnosis. Must have surgical resection planned, have a contraindication to surgery, or have malignant pheochromocytoma. For reauthorization: must have chart documentation from prescriber indicating improvement in condition.

Age Restriction

Prescriber Restriction

Coverage Duration
Initial: 90 days. Reauthorization: through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
DIFICID

Exclusion Criteria

Required Medical Information
Diagnosis of Clostridium difficile associated diarrhea (CDAD) with one of the following: A) Patient has mild to moderate CDAD and failure, contraindication or intolerance to oral Vancocin (vancomycin), or B) Patient has severe CDAD.

Age Restriction
18 years or older

Prescriber Restriction

Coverage Duration
10 Days

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documented diagnosis of A) Chronic liver disease, AND has thrombocytopenia with platelet count less than 50 x 10^9/L, AND is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy OR B) Chronic immune thrombocytopenia in patients who have had an insufficient response to a previous treatment.

Age Restriction
Greater than or equal to 18 years of age

Prescriber Restriction

Coverage Duration
End of benefit year

Other Criteria

Indications

Off Label Uses
DRONABINOL

Drugs
dronabinol

Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Treatment of chemotherapy-induced nausea and vomiting refractory to conventional antiemetic agents (i.e. ondansetron, granisetron, dexamethasone, aprepitant), or B) Treatment of anorexia associated with weight loss in patients with HIV with documented trial and failure, contraindication, or intolerance to megestrol.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria
Dronabinol is subject to Part B vs. Part D review. Part B if related to cancer treatment and is a full replacement for IV antiemetic within 48 hours of cancer treatment. Part D if related to cancer treatment after the 48-hour period, or for any other medically accepted diagnosis.

Indications
All FDA-approved Indications.

Off Label Uses
Dupixent (Dupilumab)

Drugs
DUPIXENT SUBCUTANEOUS SYRINGE 200 MG/1.14 ML, 300 MG/2 ML

Exclusion Criteria

Required Medical Information
Patient must have the following: A) Moderate-to-severe atopic dermatitis (eczema) AND submission of medical records (e.g. chart notes, laboratory values) documenting the following: Inadequate response, intolerance or contraindication to ONE medication in EACH of the following categories: a. Topical calcineurin inhibitor b. High potency topical corticosteroid. OR B) Moderate-to-severe asthma AND submission of medical records documenting the following: 1. Patient has ONE of the following: a. Asthma with eosinophilic phenotype, or b. Oral corticosteroid dependent asthma with at least 1 month of oral corticosteroid use within the last 3 months AND 2. Inadequate control of asthma symptoms after a minimum of 3 months of use of one of the following: a. Inhaled corticosteroids & long acting beta agonist, or b. Inhaled corticosteroids & long acting muscarinic antagonist. OR C) chronic rhinosinusitis with nasal polyposis.

Age Restriction
12 or older

Prescriber Restriction

Coverage Duration
Initial Authorization will be for 3 months. Reauthorization will be for 1 year.

Other Criteria
Renewals require submission of medical records (e.g. chart notes, laboratory values) documenting improvement of the condition.

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
EMSAM

Exclusion Criteria
Pheochromocytoma. Patient is taking or will take any of the following: SSRIs, SNRIs, tricyclic antidepressants (TCAs), bupropion, buspirone, meperidine, tramadol, methadone, pentazocine, dextromethorphan, St. John's wort, mirtazapine, cyclobenzaprine, oral selegiline, other MAOIs, oxcarbazepine, carbamazepine, and/or sympathomimetic amines.

Required Medical Information
Diagnosis of major depressive disorder, AND 1) Failure of at least two generic oral antidepressants from different classes(at least one should be from the following list: selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, mirtazapine, or bupropion unless contraindicated), AND 2) Patient had an adequate washout period (for patients previously on agents requiring a washout period)

Age Restriction
18 years old and greater

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Active serious infection (including tuberculosis).

Required Medical Information
Diagnosis of one of the following: A) Moderate to severe rheumatoid arthritis and patient had an inadequate response to, intolerance to, or contraindication to at least one non-biologic disease modifying anti-rheumatic drugs (DMARD) and one NSAID for at least 3 months, or B) Moderate to severe polyarticular juvenile idiopathic arthritis and patient had an inadequate response, intolerance or contraindication to at least one DMARD and one NSAID for at least 3 months, OR C) Psoriatic arthritis and patient had an inadequate response, intolerance, or contraindication to methotrexate, or D) Ankylosing spondylitis and patient had an inadequate response, intolerance or contraindication to methotrexate, or E) Moderate to severe chronic plaque psoriasis (affecting more than 5% of body surface area or affecting crucial body areas such as the hands, feet, face, or genitals) and patient had an inadequate response, intolerance or contraindication to conventional therapy with at least two NSAIDs, or preferred DMARDs include: methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide. Dosing as per FDA approved labeling.

Indications
All FDA-approved indications.

Off Label Uses
Drugs
ENDARI

Exclusion Criteria

Required Medical Information
Documented diagnosis of sickle cell disease.

Age Restriction
5 years and older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

**Required Medical Information**
Documentation of the following A) diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) or seizures associated with Dravet syndrome (DS): AND B) normal serum transaminases (ALT and AST) and total bilirubin levels: AND C) inadequate treatment response, intolerance, or contraindication to TWO generic antiepileptic medications (i.e. clobazam, Valproic acid, Lamotrigine, Levetiracetam, Topiramate, etc.)

**Age Restriction**
2 years of age or older

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year

**Other Criteria**
Dosing is within the FDA labeled dose of up to 20mg/kg/day.

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Epoetin alpha

Drugs
PROCRIT INJECTION SOLUTION 10,000 UNIT/ML, 2,000 UNIT/ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML, 40,000 UNIT/ML

Exclusion Criteria
Uncontrolled hypertension. Pure red cell aplasia that begins after ESA treatment.

Required Medical Information
Pre-treatment hemoglobin level less than 10 g/dL OR 15 g/dL for patients undergoing elective noncardiac, nonvascular surgery AND Patient has adequate iron stores prior to initiation of therapy defined as ferritin more than 100 mcg/L or serum transferrin saturation greater than 20% AND other causes of anemia such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic disease (such as sickle cell anemia, thalassemia, and porphyria) have been ruled out AND Diagnosis of one of the following: A) Anemia due to chronic kidney disease (CKD) with or without hemodialysis, OR B) Anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and two additional months of chemotherapy is anticipated, C) Treatment of anemic in a patient at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusion, D) Anemia in zidovudine-treated HIV infection with serum erythropoietin levels 500 mUnits/mL or less and zidovudine doses 4,200 mg/week or less.

Age Restriction

Prescriber Restriction
CKD - prescribed by a nephrologist or hematologist. Non-myeloid malignancies - prescribed by an oncologist/hematologist. Surgery - Prescribed by a surgeon. HIV - Prescribed by an infectious disease specialist.

Coverage Duration
Initial: 3 months. Renewal: CKD-12 months, Non-myeloid cancers, HIV-4 months. Surgery-3 months

Other Criteria
For renewal of CKD (dialysis patients): Hb less than 11 g/dL or physician will decrease or interrupt dose. For renewal of CKD (non-dialysis patients): Hb less than 10 g/dL or physician will decrease or interrupt dose. For renewal of non-myeloid malignancies: Concurrent myelosuppressive chemotherapy and Hb is 12g/dL or less and there is measurable response after eight weeks (defined as an increase in Hb 1 g/dL or more or a reduction in red blood cell transfusion requirements). For renewal of zidovudine-treated HIV, Hb is 12g/dL or less AND Zidovudine dose remains 4,200 mg/week or less and there is a measurable response after eight weeks (defined as an increase in Hb or a reduction in RBC transfusion requirements or documented dose escalation [up to max of 300 units/kg/dose]). Subject to Part D versus Part B coverage determination.

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of metastatic basal cell carcinoma OR Diagnosis of locally advanced basal cell carcinoma that has recurred following surgery or when the patient is not a candidate for surgery and radiation.

Age Restriction
18 years or older

Prescriber Restriction

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
ERLEADA

Exclusion Criteria

Required Medical Information
Documented diagnosis of non-metastatic, castration-resistant prostate cancer (NM-CRPC).

Age Restriction

Prescriber Restriction

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
ESBRIET ORAL CAPSULE, ESBRIET ORAL TABLET 267 MG, 801 MG

Exclusion Criteria

Required Medical Information
The patient has a diagnosis of idiopathic pulmonary fibrosis confirmed by a high resolution CT scan or biopsy AND the patient does not have evidence or suspicion of an alternative interstitial lung disease diagnosis AND liver function tests have been performed prior to start of therapy

Age Restriction

Prescriber Restriction
Prescribed by or in consultation with a pulmonologist

Coverage Duration
Through benefit year

Other Criteria
For renewal, patient experienced stabilization from baseline or a less than 10 percent decline in force vital capacity AND the patient has not experienced AST or ALT elevations greater than 5 times the upper limit of normal or greater than 3 times the upper limit of normal with signs or symptoms of severe liver damage.

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
EVENITY SUBCUTANEOUS SYRINGE 210MG/2.34ML (105MG/1.17MLX2)

Exclusion Criteria

Required Medical Information
Diagnosis of Osteoporosis in a postmenopausal female AND one or more of the following: 1) History of osteoporotic fracture, or 2) Documented trial and failure of bisphosphonate or 3) Documented contraindication or intolerance to bisphosphonate therapy. Patient has not received more than 1 year of therapy with Evenity.

Age Restriction

Prescriber Restriction

Coverage Duration
12 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
EVZIO INJECTION AUTO-INJECTOR 2 MG/0.4 ML

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
EXJADE

Drugs
deferasirox oral tablet, dispersible, EXJADE

Exclusion Criteria
Creatinine clearance less than 40 mL/minute. Platelet count less than 50 x 109/L. Poor performance status. Severe (Child-Pugh class C) hepatic impairment. High-risk myelodysplastic syndromes. Advanced malignancies. Gastrointestinal ulceration or hemorrhage.

Required Medical Information

Age Restriction
2 years of age or older for chronic iron overload due to transfusions. 10 years of age or older for chronic iron overload due to NTDT.

Prescriber Restriction

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
FARYDAK ORAL CAPSULE 10 MG, 20 MG

Exclusion Criteria

Required Medical Information
Clinically diagnosed with multiple myeloma. Trial and failure of at least two prior treatment regimens, including bortezomib and an immunomodulatory agent. Must be used in combination with bortezomib and dexamethasone.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
FASENRA, FASENRA PEN

Exclusion Criteria

Required Medical Information
Documentation that the patient has asthma with an eosinophilic phenotype defined as blood eosinophils greater than or equal to 300 cells/µL within previous 12 months or greater than or equal to 150 cells/µL within 6 weeks of dosing AND medication will be used in combination with a corticosteroid inhaler and long acting beta2-agonist AND Patient must have experienced two or more exacerbations in the previous year OR require daily oral corticosteroids

Age Restriction

Prescriber Restriction

Coverage Duration
6 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs

clozapine oral tablet, disintegrating

Exclusion Criteria
If the patient has any of the following contraindications: agranulocytosis, bone marrow suppression, coma, ileus, leukopenia, myocarditis or neutropenia, OR if the patient has CNS depression, dementia-related psychosis or uncontrolled epilepsy.

Required Medical Information
A statement showing the patient is unwilling or unable to take tablets or capsules orally or at high risk for non-compliance AND is not receiving other tablets or capsules indicating that the patient can take non-dissolvable tablets.

Age Restriction

Prescriber Restriction
Part of a clozapine registry.

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
FENTANYL CITRATE BUCCAL

Drugs
fentanyl citrate buccal lozenge on a handle

Exclusion Criteria
Management of acute or post-operative pain, including headache/migraine, dental pain, or use in the emergency room. Opioid non-tolerant patients.

Required Medical Information
Diagnosis of cancer AND 1. Use is for breakthrough cancer pain, AND 2. Patient is opioid tolerant and taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer, AND 3. At least TWO other formulary short-acting strong narcotic analgesic alternatives (e.g. hydrocodone/acetaminophen, hydromorphone, morphine, oxycodone, oxycodone/acetaminophen) have been ineffective, not tolerated, or contraindicated, AND 4. Prescriber is registered in the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy Access program.

Age Restriction
16 years or older

Prescriber Restriction
Prescribed by an oncologist or pain specialist.

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses

71
**FERRIPROX**

**Drugs**
**FERRIPROX ORAL TABLET**

**Exclusion Criteria**

**Required Medical Information**
Diagnosis of transfusional iron overload due to thalassemia syndromes AND patient has failed prior chelation therapy with Desferal or Exjade (failure is defined as a serum ferritin level greater than 2,500 mcg/L) or patient has a contraindication or intolerance to Desferal or Exjade AND Patient has an absolute neutrophil count greater than 1.5 x 10⁹/L.

**Age Restriction**

**Prescriber Restriction**
Prescribed by a hematologist/oncologist or hepatologist

**Coverage Duration**
Through benefit year

**Other Criteria**
For renewal, patient has experienced at least a 20% reduction in serum ferritin levels and has an absolute neutrophil count greater than 0.5 x 10⁹/L

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria

Required Medical Information
Documented trial of any two generic antidepressants (e.g. bupropion, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, paroxetine CR, sertraline, duloxetine, venlafaxine).

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year,

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
FIRAZYR, icatibant

Exclusion Criteria

Required Medical Information
Documentation of clinical diagnosis of hereditary angioedema or C1 inhibitor deficiency and having angioedema attacks.

Age Restriction

Prescriber Restriction
Must be prescribed by an allergist, immunologist, hematologist, or a physician that specializes in the treatment of HAE or related disorders.

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Firdapse (Amidampridine)

Drugs
FIRDAPSE

Exclusion Criteria
Member has a history of seizures

Required Medical Information
The diagnosis has been confirmed by one of the following: A) Presence of anti-P/Q-type voltage-gated calcium channel (VGCC) antibodies OR B) Characteristic electromyography (EMG).

Age Restriction

Prescriber Restriction
Neurologist

Coverage Duration
Through the benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
FORTEO

Exclusion Criteria
Because of an increased incidence of osteosarcoma, Forteo should not be prescribed for patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, or prior radiation therapy involving the skeleton).

Required Medical Information
Diagnosis of one of the following: A) Osteoporosis in a postmenopausal female, or B) Primary or hypogonadal osteoporosis in a male, or C) Osteoporosis associated with sustained systemic glucocorticoid therapy AND one or more of the following: 1) History of osteoporotic fracture, or 2) Documented trial and failure of bisphosphonate and Prolia, or 3) Documented contraindication or intolerance to bisphosphonate therapy and Prolia. Patient has not received more than 2 years of therapy with Forteo.

Age Restriction

Prescriber Restriction

Coverage Duration
Initial: 1 year. Renewal: 1 year not to exceed 2 years of total therapy.

Other Criteria
Treatment failure is defined as documented continued bone loss after at least three months despite treatment with a bisphosphonate or Prolia. Note: Since the effects of long-term treatment with Forteo are not known at this time, therapy for more than 2 years duration is considered experimental and investigational.

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
FYCOMPA ORAL SUSPENSION, FYCOMPA ORAL TABLET 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG

Exclusion Criteria

Required Medical Information
Documented diagnosis of partial-onset seizure or primary generalized tonic-clonic seizures AND treatment failure of at least two other formulary medications used in the treatment of provided diagnosis.

Age Restriction
4 years of age and older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
GARDASIL 9 (PF)

Exclusion Criteria

Required Medical Information
Patient age

Age Restriction
Must be between 9 and 45 years of age

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
Dosing 0.5 ml/dose IM. Give the first dose at an elected date, the second dose 2 months after the first, and the third dose 6 months after the first dose. The vaccine is not intended to be used for treatment of active external genital lesions: cervical, vulvar, vaginal, and anal cancers. CIN. VIN. VaIN. or AIN.

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
GATTEX 30-VIAL

Exclusion Criteria
Active gastrointestinal malignancy (gastrointestinal tract, hepatobiliary, pancreatic), colorectal cancer, or small bowel cancer

Required Medical Information
Diagnosis of short bowel syndrome AND patient is receiving specialized nutritional support (i.e. parenteral nutrition)

Age Restriction
1 years of age or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
For renewal, patient has a reduced need for parenteral support (20% reduction) after at least 6 months of therapy.

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
GILENYA ORAL CAPSULE 0.5 MG

Exclusion Criteria
Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. Baseline QTc interval greater than or equal to 500 ms. Receiving concurrent treatment with Class la or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol). Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

Required Medical Information
Diagnosis of a relapsing form of multiple sclerosis or diagnosis of first clinical episode with MRI features consistent with MS AND Patient will be observed for signs and symptoms of bradycardia in a controlled setting for at least 6 hours after the first dose.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
GILOTIRIF

Exclusion Criteria

Required Medical Information
Documented diagnosis of 1) Metastatic non-small cell lung cancer (NSCLC) with tumors that have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test OR 2) Metastatic squamous non-small cell lung cancer progressing after platinum-based chemotherapy.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
GLEEVEC (imatinib mesylate)

**Drugs**
*imatinib oral tablet 100 mg, 400 mg*

**Exclusion Criteria**

**Required Medical Information**
Diagnosis of one of the following: 
A) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), or 
B) Ph+ acute lymphoblastic leukemia (ALL), or 
C) Gastrointestinal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy, or 
D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, or 
E) Hypereosinophilic syndrome or chronic eosinophilic leukemia, or 
F) Myelodysplastic syndrome or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements, or 
G) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutation or with c-KIT mutational status unknown.

**Age Restriction**
1 year of age or older - newly diagnosed CML in the chronic phase or newly diagnosed Ph+ ALL. 18 years of age or older for other indications.

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria

**Required Medical Information**
Documented diagnosis of non-24-hour sleep-wake disorder (non-24) AND member is totally blind.

**Age Restriction**
18 years of age and older

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
disopyramide phosphate oral capsule

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication

Age Restriction
PA applies to patients 65 years or older.

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
HRM - ANTIHISTAMINES

Drugs
- clemastine oral tablet 2.68 mg
- cyproheptadine oral tablet
- hydroxyzine HCl oral solution 10 mg/5 mL
- PHENADOZ RECTAL SUPPOSITORY 12.5 MG
- promethazine oral
- promethazine rectal suppository 12.5 mg, 25 mg
- PROMETHEGAN RECTAL SUPPOSITORY 25 MG, 50 MG

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
trihexyphenidyl

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
HRM - ANTIPSYCHOTICS

Drugs
thioridazine

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA).

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
Applies to New Starts only. Non-HRM alternatives include: quetiapine, risperidone, aripiprazole, asenapine, olanzapine, ziprasidone

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
  phenobarbital

Exclusion Criteria

Required Medical Information
Verify the medication is being used for an FDA-approved diagnosis.

Age Restriction
PA applies to patients 65 years and older.

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
DRUGS
nifedipine oral capsule

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA).

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
Non-HRM alternatives include: extended-release nifedipine, nicardipine, amlodipine

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
meprobamate

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication.

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
megestrol oral suspension 400 mg/10 mL (40 mg/mL), megestrol oral tablet

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication.

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
Applies to New Starts only.

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
DUAVEE, estradiol oral, estradiol transdermal patch semiweekly, estradiol transdermal patch weekly, estradiol-norethindrone acet oral tablet 1-0.5 mg, MENEST ORAL TABLET 0.3 MG, 0.625 MG, 1.25 MG, PREMARIN ORAL, PREMPHASE, PREMPRO

Exclusion Criteria

Required Medical Information
Medical documentation of FDA-approved indication, AND trial and failure or contraindication to two preferred alternatives for established indication. Preferred alternatives include: Vasomotor symptoms of menopause: requires provider acknowledgement of HRM status, Vulvar or vaginal atrophy: Premarin cream, Osteoporosis: alendronate, ibandronate, raloxifene.

Age Restriction
PÅ applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
HRM - PLATELET INHIBITORS

Drugs
dipyridamole oral

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA).

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
A trial and failure of clopidogrel is required prior to approval of dipyridamole.

Indications
All FDA-approved Indications.

Off Label Uses
HRM - SKELETAL MUSCLE RELAXANTS

Drugs
cyclobenzaprine oral tablet 10 mg, 5 mg, methocarbamol oral

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication.

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
glyburide micronized oral tablet 1.5 mg, 3 mg, 6 mg, glyburide oral tablet 1.25 mg, 2.5 mg, 5 mg, glyburide-metformin oral tablet 1.25-250 mg, 2.5-500 mg, 5-500 mg

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA).

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
Non-HRM alternatives include: glimepiride, glipizide

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
- amitriptyline, clomipramine, doxepin oral capsule, doxepin oral concentrate, imipramine HCl, perphenazine-amitriptyline

Exclusion Criteria

Required Medical Information
The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA).

Age Restriction
PA applies to patients 65 years or older

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
Applies to New Starts only. Non-HRM alternatives include: nortriptyline, desipramine, trazodone, SSRIs (fluoxetine, paroxetine, citalopram, escitalopram), SNRIs (venlafaxine, duloxetine), mirtazapine, bupropion.

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of 1 of the following: A) Mod-severe rheumatoid arthritis and trial of 1 or more non-biologic disease modifying anti-rheumatic drugs (DMARD) (e.g., hydroxychloroquine [HCQ], sulfasalazine, methotrexate [MTX], leflunomide, azathioprine, cyclosporine) for at least 3 months, or B) Mod-severe polyarticular juvenile idiopathic arthritis (JIA) and trial of 1 or more non-biologic DMARDs (e.g., HCQ, sulfasalazine, MTX, leflunomide, azathioprine, cyclosporine) for at least 3 months, or C) Psoriatic arthritis and trial of MTX, or D) Ankylosing spondylitis and trial of 1 or more NSAIDs, or E) Mod-severe chronic plaque psoriasis (affecting more than 5% of body surface area or crucial body areas such as the hands, feet, face, or genitals) and trial of at least 1 of the following: phototherapy (including but not limited to Ultraviolet A with a psoralen [PUVA] and/or retinoids [RePUVA] for at least 1 continuous month or 1 or more oral systemic treatments (e.g., MTX, cyclosporine, acitretin, sulfasalazine) for at least 3 months, or F) Mod-severe Crohn's disease and trial of 2 or more of the following: corticosteroids (e.g., prednisone, methylprednisolone) or non-biologic DMARDs (e.g., azathioprine, MTX, mercaptopurine), or G) Mod-severe ulcerative colitis trial of 2 or more of the following: corticosteroids (e.g., prednisone, methylprednisolone), 5-ASA (i.e. mesalazine, sulfasalazine, balsalazide, olsalazine) or non-biologic DMARDs (azathioprine, MTX, mercaptopurine), or H) Hidradenitis suppurativa, or I) Non-infectious intermediate, posterior, and panuveitis and trial of 1 or more of the following: periocular, intraocular, or systemic corticosteroids, immunosuppressants (azathioprine, MTX, mycophenolate mofetil, cyclophosphamide, cyclosporine). A trial is defined as an inadequate response, intolerance or contraindication to the therapy.

Age Restriction
2 years of age or older for JIA or uveitis. 6 years of age and older for pediatric Crohn's disease. 12 years of age or older for hidradenitis suppurativa. 18 years of age or older for all other indications.

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with: 1) an aromatase inhibitor as initial endocrine based therapy in postmenopausal women OR 2) fulvestrant in women with disease progression following endocrine therapy OR 3) an aromatase inhibitor in men with advanced or metastatic breast cancer.

Age Restriction

Prescriber Restriction

Coverage Duration
Through benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
ICLUSIG

Drugs
ICLUSIG ORAL TABLET 15 MG, 45 MG

Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Chronic myelogenous leukemia (CML) and patient has tried and failed or has an intolerance to two first-line tyrosine kinase inhibitors OR patient has a known T315I mutation, or B) Philadelphia chromosome-positive acute lymphoblastic leukemia and the patient has tried and failed or had an intolerance to two previous tyrosine kinase inhibitors OR patient has a known T315I mutation.

Age Restriction
18 years or older

Prescriber Restriction
Prescribed by a hematologist/oncologist

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
IDHiFA

Exclusion Criteria

Required Medical Information
1. Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation AND 2. Prescriber agrees to monitor for signs and symptoms of differentiation syndrome.

Age Restriction

Prescriber Restriction
Oncologist or Hematologist

Coverage Duration
Through the end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
IMBRUVICA ORAL CAPSULE 140 MG, 70 MG, IMBRUVICA ORAL TABLET

Exclusion Criteria

Required Medical Information
Documented diagnosis of 1) Mantle Cell Lymphoma and has received at least one prior therapy, OR 2) chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), OR 3) Waldenström's macroglobulinemia, OR 4) marginal zone lymphoma (MZL) and have received at least one prior anti-CD20-based therapy, OR 5) chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

Age Restriction
18 years of age and older

Prescriber Restriction

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Inbrija (levodopa inhalation)

Drugs
INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE

Exclusion Criteria
patient is not currently taking or has recently (within 2 weeks) taken a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine and tranylcypromine)

Required Medical Information
Patient is currently treated with carbidopa/levodopa AND is experiencing intermittent OFF episodes secondary to Parkinson's disease

Age Restriction

Prescriber Restriction

Coverage Duration
3 months

Other Criteria
Reauthorization requires physician attestation of medications efficacy

Indications
All FDA-approved Indications.

Off Label Uses
**Exclusion Criteria**
Closed epiphyses. Active or suspected malignancy.

**Required Medical Information**
Diagnosis of one of the following: A) Severe primary IGF-1 deficiency, defined as height standard deviation score (SDS) less than or equal to -3.0 AND basal IGF-1 SDS less than or equal to -3.0 AND normal or elevated growth hormone, or B) Growth hormone deletion with development of neutralizing antibodies to growth hormone AND other causes of IGF-1 deficiency (e.g., hypothyroidism, nutritional deficiencies, pituitary disorders, etc.) have been ruled out or corrected prior to initiating therapy.

**Age Restriction**

**Prescriber Restriction**
Pediatric endocrinologist

**Coverage Duration**
6 months to 1 year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
INGREZZA, INGREZZA INITIATION PACK

Exclusion Criteria

Required Medical Information
Clinical documentation of FDA indication for treatment.

Age Restriction
18 years of age and older

Prescriber Restriction

Coverage Duration
Through the end of the benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
INLYTA ORAL TABLET 1 MG, 5 MG

Exclusion Criteria

Required Medical Information
Diagnosis of advanced renal cell carcinoma AND patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens)

Age Restriction
18 years of age or older

Prescriber Restriction

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
INREBIC

Exclusion Criteria
Patients on treatment with ruxolitinib before initiation must taper and discontinue according to ruxolitinib prescribing information

Required Medical Information
Must provide labs showing patient is not thiamine deficient before starting drug

Age Restriction
18 years of age and older

Prescriber Restriction
Oncologist or Hematologist

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Type B viral Hepatitis (HBeAg positive): Serum HBsAg positive for at least six months, AND elevated serum ALT 2 times ULN or moderate to severe hepatitis or fibrosis on biopsy. Type B Viral Hepatitis (HBeAg negative) HBsAG positive for at least 6 months AND BHV DNA level of 2000 IU/ml or more than 11,200 copies/ml AND One of the following, persistent ALT 2 times UNL or moderate to severe hepatitis or fibrosis on biopsy. Documentation must be provided showing trial and failure to our preferred agent Peg-Intron. Chronic Hepatitis C: Positive HCV antibody and HCV RNA. Documentation must be provided showing trial and failure to our preferred agent Peg-Intron. Condyloma Acuminatum or Perianal Warts: Must have documentation of trial and failure to preferred alternative or intolerance/contraindication to preferred alternatives. For external perianal warts, condylox gel, for external genital warts, podofilox, or imiquimod. Hairy Cell Leukemia: Medical documentation indicating diagnosis. Malignant Melanoma: Indicated as adjuvant to surgical treatment with malignant melanoma who are free of disease but at high risk for systemic recurrence, within 56 days of surgery. Follicular Lymphoma: Indicated for the initial treatment of clinically aggressive follicular Non-Hodgkins Lymphoma in conjunction with anthracycline-containing combination chemotherapy. Efficacy in patients with low-grade, low-tumor burden follicular Non-Hodgkins Lymphoma has not been demonstrated. AIDS-Related Kaposis Sarcoma: Indicated for the treatment of selected patients. The likelihood of response to therapy is greater in patients who are without systemic symptoms, who have limited lymphadenopathy and who have a relatively intact immune system as indicated by total CD4 count.

Age Restriction
For Hepatitis B- age 1 or older, For Hepatitis C - age 3 or older, All other diagnoses- 18 years or older.

Prescriber Restriction

Coverage Duration
1 year

Other Criteria
Medication is eligible for B vs. D determination

Indications
All FDA-approved Indications.
Drugs
INVEGA SUSTENNA INTRAMUSCULAR SYRINGE 117 MG/0.75 ML, 156 MG/ML, 234 MG/1.5 ML, 39 MG/0.25 ML, 78 MG/0.5 ML, paliperidone oral tablet extended release 24hr 1.5 mg, 3 mg, 6 mg, 9 mg

Exclusion Criteria

Required Medical Information
Diagnosis of Schizophrenia OR Schizoaffective Disorder AND documented treatment failure or intolerable side effects from treatment with two formulary antipsychotic medications such as risperidone, ziprasidone, quetiapine.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
IRESSA (gefitinib)

Drugs
IRESSA

Exclusion Criteria

Required Medical Information
Clinically diagnosed with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Age Restriction
18 years of age or older

Prescriber Restriction
Prescribed by an oncologist or a hematologist

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
ITRACONAZOLE

Drugs
itraconazole oral capsule

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of A) acute graft-versus-host disease (GVHD) OR B) polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea OR C) intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia veramyelofibrosis and post-essential thrombocytemiamyelofibrosis AND lab work indicating a complete blood count and platelet count before initiating therapy AND recent lab work indicating complete blood count AND platelet count for a dosage adjustment. Lab work must indicate platelets are more than 50 x 10^9/L and dose must be less than 50 mg per day. No dose increases will be approved within 4 weeks of therapy and not more frequently than every 2 weeks. If no spleen reduction or symptom improvement after 6 months then discontinue the drug.

Age Restriction
12 years or older

Prescriber Restriction

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
JUXTAPID

Exclusion Criteria
Pregnancy. Concomitant administration of moderate or strong CYP3A4 inhibitors (e.g., clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinalvir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telithromycin, voriconazole, amprenavir, aprepitant, atazanavir, ciprofloxacin, crizotinib, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil, etc.). Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests. Dosage regimen above 60 mg per day.

Required Medical Information
Diagnosis of homozygous familial hypercholesterolemia as evidenced by one of the following: A) genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or autosomal recessive hypercholesterolemia (ARH) adaptor protein gene locus OR B) untreated/pre-treatment LDL greater than 500 mg/dL with at least one of the following: 1) cutaneous or tendonous xanthoma before 10 years of age, OR 2) untreated LDL cholesterol levels consistent with heterozygous FH in both parents (greater than 190 mg/dL), AND Patient has tried and had an inadequate response to the maximum tolerated dose of a high potency statin (e.g., atorvastatin, rosuvastatin), unless statin contraindicated or statin intolerant, and a PCSK9 (e.g., Praluent, Repatha).

Age Restriction
18 years of age and older

Prescriber Restriction
Provider and patient must be registered in the Juxtapid REMS program

Coverage Duration
Initial: 6 months, Reauthorization: through benefit year

Other Criteria
Indications
All FDA-approved Indications.

Off Label Uses
Drugs
JYNARQUE ORAL TABLETS, SEQUENTIAL

Exclusion Criteria

Required Medical Information
Medication requested is being used to slow kidney function decline AND Liver function laboratory values (ALT, AST and bilirubin) have been reviewed and are appropriate before initiation.

Age Restriction
Patient is 18 years of age or older

Prescriber Restriction

Coverage Duration
Initial Authorization will be for 3 months. Reauthorization will be for 1 year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
KALYDECO ORAL GRANULES IN PACKET 25 MG, 50 MG, 75 MG, KALYDECO ORAL TABLET

Exclusion Criteria

Required Medical Information
Medical documentation of cystic fibrosis AND member has one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data.

Age Restriction
Ivacaftor oral granules are approved in patients 6 months of age and older. Ivacaftor oral tablets are approved in patients 6 years of age and older.

Prescriber Restriction
Endocrinologist or Pulmonologist

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
KISQALI FEMARA CO-PACK ORAL TABLET 200 MG/DAY (200 MG X 1)-2.5 MG, 400 MG/DAY (200 MG X 2)-2.5 MG, 600 MG/DAY (200 MG X 3)-2.5 MG, KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)

Exclusion Criteria

Required Medical Information
Documented diagnosis of: A) hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer AND the medication will be used in combination with an aromatase inhibitor as initial endocrine-based therapy, or B) hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer AND the patient is postmenopausal AND the medication will be used in combination with fulvestrant (only applies to single agent Kisqali).

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Pregnancy Category X and for patients who require concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses (e.g., immunosuppression after organ transplantation).

Required Medical Information
Stated diagnosis to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushings syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushings syndrome. Do not exceed 20 mg/kg per day.

Age Restriction
18 years and older

Prescriber Restriction
Endocrinologist

Coverage Duration
Through benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
KUVAN

Drugs
KUVAN ORAL TABLET, SOLUBLE

Exclusion Criteria

Required Medical Information
Documented diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU).

Age Restriction
1 month and older

Prescriber Restriction

Coverage Duration
Initial: 2 months. Renewal: through end of benefit year

Other Criteria
For initial approval, Patient will have phenylalanine levels measured one week after starting therapy and periodically for up to two months of therapy to determine response. For renewal, patient has been determined to be a responder to therapy (i.e. phenylalanine levels have decreased by at least 30% from baseline) and phenylalanine levels will be measured periodically during therapy.

Indications
All FDA-approved Indications.

Off Label Uses
LATUDA (lurasidone)

Drugs
LATUDA ORAL TABLET 120 MG, 20 MG, 40 MG, 60 MG, 80 MG

Exclusion Criteria

Required Medical Information
Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
*ledipasvir-sofosbuvir*

Exclusion Criteria

**Required Medical Information**
Provider must submit medical records documenting the following: 1) medical diagnosis of Chronic Hepatitis C with labs documenting genotype and subtype, AND 2) medical records documenting viral load taken within 6 months of beginning therapy, AND 3) fibrosis score to confirm appropriate duration of treatment, AND 4) documentation of previous HCV therapies to confirm appropriate duration of treatment.

**Age Restriction**
Patient must be 12 years of age or older

**Prescriber Restriction**
Prescribed by, a gastroenterologist, hepatologist, or infectious disease physician.

**Coverage Duration**
12 to 24 weeks based on the AASLD treatment guidelines

**Other Criteria**
Criteria and coverage durations will be applied consistent with current AASLD/IDSA guidance.

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
LENVIMA ORAL CAPSULE 10 MG/DAY (10 MG X 1), 12 MG/DAY (4 MG X 3), 14 MG/DAY (10 MG X 1-4 MG X 1), 18 MG/DAY (10 MG X 1-4 MG X 2), 20 MG/DAY (10 MG X 2), 24 MG/DAY (10 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY (4 MG X 2)

Exclusion Criteria

Required Medical Information
Documented diagnosis of: 1) locally recurrent or metastatic, progressive, radioactive iodine-refractory Differentiated Thyroid Cancer OR, 2) Advanced Renal Cell Carcinoma and medication will be used in combination with everolimus following one prior anti-angiogenic therapy, OR 3) unresectable hepatocellular carcinoma (HCC).

Age Restriction

Prescriber Restriction

Coverage Duration
Through benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
ambrisentan, LETAIRIS

Exclusion Criteria
Known or suspected pregnancy. Treat women of child-bearing potential only after a negative pregnancy test and treat only women who are using two reliable methods of contraception OR have had a tubal sterilization OR a Copper T 380A IUD or LNG 20 IUD inserted.

Required Medical Information
Diagnosis of Pulmonary Arterial Hypertension (PAH) WHO Group 1 that was confirmed by right heart catheterization, AND Patient has WHO Functional Class II - IV symptoms, AND The patient has had a vasoreactivity test unless the provider indicates that the patient has a contraindication to the test or indicates clinical inappropriateness to the vasoreactivity test, AND Must have tried and failed or has a contraindication to the use of a calcium channel blocker if they have a positive vasoreactivity test, AND If functional class II or III, must have tried and failed or intolerant to sildenafil, or provide documentation as to why contraindicated to initiation of sildenafil.

Age Restriction
18 years and older

Prescriber Restriction
Prescribed by a pulmonologist, a cardiologist, or a physician specializing in pulmonary arterial hypertension.

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Chemotherapy or radiotherapy within 24 hours or concomitantly, excess leukemic myeloid blasts in the bone marrow or
time, hypersensitivity to granulocyte-macrophage colony-stimulating factor (GM-CSF) or yeast-derived products, allergic or anaphylactoid reactions to the medication in the past.

Required Medical Information
Diagnosis of one of the following: A) Patient has undergone allogeneic or autologous bone marrow transplant (BMT) and
engraftment is delayed or failed and patient does not have excessive leukemic myeloid blasts in bone marrow/peripheral
blood (more than 10%), or B) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize
progenitor cells for collection by leukapheresis, or C) Medication will be used for myeloid reconstitution after an
autologous or allogeneic BMT, or D) Patient has acute myeloid leukemia and administration will be after completion of
induction chemotherapy.

Age Restriction

Prescriber Restriction
Oncologist or Hematologist

Coverage Duration
Through end of benefit year

Other Criteria
This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be
submitted describing the use and setting of the drug to make the determination. Home or LTC administration covered
under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.

Indications
All FDA-approved Indications.

Off Label Uses
LIDOCAINE PRODUCTS

Drugs
lidocaine topical adhesive patch, medicated 5%, lidocaine topical ointment

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Lokelma (Sodium Zirconium Cyclosilicate)

Drugs
LOKELMA

Exclusion Criteria

Required Medical Information
Documentation of elevated serum potassium (greater than 5.0 mEq/L) and the beneficiary has failure, contraindication or intolerance to sodium polystyrene sulfonate oral suspension.

Age Restriction
18 years and older

Prescriber Restriction

Coverage Duration
6 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
LONSURF (TIPIRACIL/Trifluridine)

Drugs
LONSURF ORAL TABLET 15-6.14 MG, 20-8.19 MG

Exclusion Criteria

Required Medical Information
Documented diagnosis of 1) metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy OR 2) metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/NEU-targeted therapy.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
LORBRENA ORAL TABLET 100 MG, 25 MG

Exclusion Criteria

Required Medical Information
Documentation of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on one of the following: 1. crizotinib and at least one other ALK inhibitor for metastatic disease: or 2. alectinib as the first ALK inhibitor therapy for metastatic disease: or 3. ceritinib as the first ALK inhibitor therapy for metastatic disease.

Age Restriction

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
LUPRON DEPOT, LUPRON DEPOT (3 MONTH), LUPRON DEPOT (4 MONTH), LUPRON DEPOT (6 MONTH)

Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Advanced or metastatic prostate cancer (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), or B) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only) AND 1. For initial authorization, patient has had an inadequate pain control response or has an intolerance or contraindication to one of the following: Danazol or combination [estrogen/progesterone] oral contraceptives or progestins, or 2. For retreatment course, patient is experiencing recurrence of symptoms after an initial course of therapy with leuprolide acetate and norethindrone acetate 5 mg daily will be co-administered, or C) Anemia due to uterine Leiomyomata (Fibroids) (3.75 mg 1-month &11.25 mg 3-month depots only) AND patient is preoperative, or D) Central precocious puberty (Lupron Depot-Ped) AND submission of pubertal gonadal sex steroid levels (testosterone greater than 30 ng/dL, estradiol greater than 20 pg/mL AND a pubertal LH increase upon native GnRH stimulation AND pelvic ultrasound assessment (girls) is required for approval along with notes indicating premature development of secondary sexual characteristics at or before the age of 8 yrs in girls and 9 yrs in boys and significant advancement of bone age and/or a poor adult height prediction AND other causes of sexual precocity must be excluded.

Age Restriction

Prescriber Restriction
Oncologist, Endocrinologist, Urologist, or Gynecologist to prescribe

Coverage Duration
Prostate cancer: through benefit year, Uterine Leiomyoma: 3 months, All other indications: 6 months

Other Criteria
For endometriosis and uterine fibroids, patient will be using nonhormonal contraception during and for 12 weeks after therapy.

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
LYNPARZA ORAL TABLET

Exclusion Criteria

Required Medical Information
1. Documentation of deleterious germline BRCA mutated ovarian cancer AND 2. Documentation of at least 3 prior chemotherapy regimens that have been ineffective or not tolerated AND 3. Lynparza will be used as monotherapy.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
MAVENCLAD (10 TABLET PACK), MAVENCLAD (4 TABLET PACK), MAVENCLAD (5 TABLET PACK), MAVENCLAD (6 TABLET PACK), MAVENCLAD (7 TABLET PACK), MAVENCLAD (8 TABLET PACK), MAVENCLAD (9 TABLET PACK)

Exclusion Criteria
Individual with current malignancy OR human immunodeficiency virus (HIV) infection OR an active chronic infection (e.g., hepatitis or tuberculosis)

Required Medical Information
Documentation of diagnosis of relapsing multiple sclerosis, including relapsing-remitting disease or active secondary progressive disease AND the patient has had a trial and inadequate response or intolerance to at least one alternative drug indicated for the treatment of multiple sclerosis.

Age Restriction

Prescriber Restriction

Coverage Duration
1 year

Other Criteria
Will only be approved for 2 treatment cycles.

Indications
All FDA-approved Indications.

Off Label Uses
Mavyret

Drugs
MAVYRET

Exclusion Criteria

Required Medical Information
Provider must submit medical records documenting the following: 1) medical diagnosis of Chronic Hepatitis C with labs documenting genotype and subtype, AND 2) medical records documenting viral load taken within 6 months of beginning therapy, AND 3) fibrosis score to confirm appropriate duration of treatment, AND 4) documentation of previous HCV therapies to confirm appropriate duration of treatment. Authorization for retreatment requires the following: 1) Evidence of failure to achieve a sustained virologic response (SVR) or lack of efficacy during treatment (polymerase chain reaction (PCR) assay, 12 or more weeks after completing treatment or a 10-fold increase of viral load at week 6 of treatment) OR evidence of adverse event that required therapy discontinuation (Laboratory results and/or clinical presentation).

Age Restriction

Prescriber Restriction
Prescribed by, a gastroenterologist, hepatologist, or infectious disease physician.

Coverage Duration
based on the AASLD treatment guidelines

Other Criteria
Criteria and coverage durations will be applied consistent with current AASLD/IDSA guidance.

Indications
All FDA-approved Indications.

Off Label Uses
MEKINIST

Drugs
MEKINIST ORAL TABLET 0.5 MG, 2 MG

Exclusion Criteria

Required Medical Information
Diagnosis of unresectable or metastatic melanoma, positive BRAF V600E or V600K mutation as detected by an FDA-approved test (THxID-BRAF Kit) or Clinical Laboratory Improvement Amendments (CLIA)-approved facility, and the patient has not received prior BRAF-inhibitor therapy.

Age Restriction
18 years or older

Prescriber Restriction
Oncologist

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Mektovi (Binimetinib)

Drugs
MEKTOVI

Exclusion Criteria

Required Medical Information
Documentation of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test and that Mektovi will be used in combination with encorafenib.

Age Restriction

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Clinical documentation of narcolepsy, obstructive sleep apnea, or shift work sleep disorder.

Age Restriction

Prescriber Restriction
Idiopathic hypersomnia-- approve if the diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center)

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.
MOLINDONE

Drugs
molindone

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
**NATPARA**

**Drugs**
NATPARA

**Exclusion Criteria**
Because of the potential risk of osteosarcoma, recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone, has not been studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations or in patients with acute postsurgical hypoparathyroidism.

**Required Medical Information**
Documented diagnosis of hypocalcemia secondary to hypoparathyroidism.

**Age Restriction**
18 years and older

**Prescriber Restriction**

**Coverage Duration**
Through benefit year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
NERLYNX

Drugs
NERLYNX

Exclusion Criteria

Required Medical Information
NERLYNX is indicated for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab based therapy.

Age Restriction

Prescriber Restriction
Oncologist

Coverage Duration
Through the end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

**Required Medical Information**
For use as primary prophylaxis of febrile neutropenia (FN) in one of the following patients: A) Patient has a 20% or higher risk of FN based on chemotherapy regimen OR B) Patient has a less than 20% risk of developing FN based on chemotherapy regimen AND at least one of the following risk factors are present: 65 years or older, Poor performance status, Poor nutritional status, Previous episodes of febrile neutropenia, Extensive prior treatment including large radiation ports, Cytopenias due to bone marrow involvement by tumor, Administration of combined chemoradiotherapy, Presence of open wounds or active infections, Other serious comorbidities (including renal or liver dysfunction notably elevated bilirubin), or C) Patient is receiving a dose-dense chemotherapy regimen in breast cancer, small cell lung cancer, or non-Hodgkin's lymphoma.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**
3 months and is renewable in situations where it continues to provide clinical benefit

**Other Criteria**
Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. Forward to clinical pharmacist to review.

**Indications**
All FDA-approved Indications.

**Off Label Uses**
**Exclusion Criteria**
Combination use with other tyrosine kinase inhibitors such as sorafenib, sunitinib. Squamous cell lung cancer being treated with carboplatin and paclitaxel.

**Required Medical Information**
Diagnosis of one of the following: A) Advanced renal cell carcinoma, or B) Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment, or C) Unresectable hepatocellular carcinoma.

**Age Restriction**
Patient must be at least 18 years old or older.

**Prescriber Restriction**

**Coverage Duration**
Initial: 3 months, Renewal: through end of benefit year w/ stable disease

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria

**Required Medical Information**
Diagnosis of multiple myeloma AND have received at least one prior therapy AND medication will be used in combination with dexamethasone and lenalidomide.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year.

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
NORTHERA

Drugs
NORTHERA

Exclusion Criteria

Required Medical Information
Documentation that patient has a persistent, consistent decrease in systolic blood pressure within 3 minutes of standing AND Northera will be used for patients with neurogenic orthostatic hypotension associated with one of the following diagnoses: 1) Primary autonomic failure due to Parkinson’s disease, multiple system atrophy, or pure autonomic failure, OR 2) Dopamine beta hydroxylase deficiency, OR 3) Non-diabetic autonomic neuropathy.

Age Restriction
18 years of age or older

Prescriber Restriction

Coverage Duration
Through benefit year

Other Criteria
For renewal, Patient does not have persistent or sustained supine hypertension (SBP more than 180 mmHg or DBP more than 110 mmHg), Patient does not have persistent or sustained standing or sitting hypertension (SBP more than 180 mmHg or DBP more than 110 mmHg), and Patient had improvement in symptoms of NOH. Sustained mean elevated blood pressure that persists for longer than 5 minutes after change in position. Persistent means elevated BP that occurs on more than one occasion on separate physician office visits

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documentation that the medication will be used as an adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes.

Age Restriction

Prescriber Restriction
Neurologist for initial prescription

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
NUBEQA- darolutamide

Drugs
NUBEQA

Exclusion Criteria

Required Medical Information
Documented non-metastatic castration resistant prostate cancer (nmCRPC).

Age Restriction

Prescriber Restriction
Oncologist

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Nucala (mepolizumab)

Exclusion Criteria

Required Medical Information
Documentation that either A) patient has asthma with an eosinophilic phenotype defined as blood eosinophils greater than or equal to 300 cells/µL within previous 12 months or greater than or equal to 150 cells/µL within 6 weeks of dosing AND medication will be used in combination with a corticosteroid inhaler and long acting beta2-agonist AND Patient must have experienced two or more exacerbations in the previous year OR require daily oral corticosteroids OR B)patient has eosinophilic granulomatosis with polyangiitis (EGPA)AND documented trial and failure of or contraindication to treatment with at least one immunosuppressants (azathioprine, cyclophosphamide, or methotrexate).

Age Restriction

Prescriber Restriction

Coverage Duration
6 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Nuedexta

Drugs
NUDEXTA

Exclusion Criteria
Currently prescribed an MAOI or within 14 days of stopping an MAOI. Diagnosis of AV block (without implanted pacemaker, or patients at high risk of complete AV block), heart failure, QT prolongation or history of torsades de pointes. Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozide).

Required Medical Information
Initial Authorization Requirement: Clinical diagnosis of Pseudobulbar affect (PBA) as evidenced by ALL of the following: A) PBA Symptom frequency of 4 or more episodes per day, AND B) Baseline score of at least 13 on the Center for Neurologic Studies-Lability Scale (CNS-LS), AND C) Neurologic disease or brain injury (e.g., traumatic brain injury, stroke, dementia, multiple sclerosis, amyotrophic lateral sclerosis (ALS), Parkinson’s disease). Reauthorization Requirement: Documentation of clinical benefit with decrease in episodes per day.

Age Restriction
18 years or older

Prescriber Restriction
Neurologist

Coverage Duration
Initial Authorization will be for 3 months. Reauthorization will be for 1 year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
NUPLAZID ORAL CAPSULE, NUPLAZID ORAL TABLET 10 MG

Exclusion Criteria

Required Medical Information
Documentation that diagnosis of Parkinson’s disease was made prior to the onset of psychotic symptoms.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
NUVIGIL

Drugs
armodafinil

Exclusion Criteria

Required Medical Information
Clinical documentation of narcolepsy, obstructive sleep apnea, or shift work sleep disorder.

Age Restriction
Patient must be at least 17 years or older

Prescriber Restriction
Idiopathic hypersomnia-- approve if the diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center)

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

**Required Medical Information**
Documented locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or the member is a not candidate for surgery or radiation therapy.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year.

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
OFEV

Exclusion Criteria

Required Medical Information
The patient has a diagnosis of idiopathic pulmonary fibrosis confirmed by a high resolution CT scan or biopsy AND the patient does not have evidence or suspicion of an alternative interstitial lung disease diagnosis AND liver function tests have been performed prior to start of therapy.

Age Restriction
18 years and older

Prescriber Restriction
Prescribed by or in consultation with a pulmonologist

Coverage Duration
Through benefit year

Other Criteria
For renewal, patient experienced stabilization from baseline or a less than 10 percent decline in force vital capacity AND the patient has not experienced AST or ALT elevations greater than 5 times the upper limit of normal or greater than 3 times the upper limit of normal with signs or symptoms of severe liver damage.

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
OMNITROPE SUBCUTANEOUS CARTRIDGE

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Pregnancy

Required Medical Information
Clinically diagnosed with pulmonary arterial hypertension WHO Group 1 that was confirmed by right heart catherization. Patient has WHO Functional Class II - IV symptoms, AND The patient has had a vasoreactivity test unless the provider indicates that the patient has a contraindication to the test or indicates clinical inappropriateness to the vasoreactivity test, AND Must have tried and failed or has a contraindication to the use of a calcium channel blocker if they have a positive vasoreactivity test, AND If functional class II or III, must have tried and failed or intolerant to sildenafil, or provide documentation as to why contraindicated to initiation of sildenafil.

Age Restriction
Patient must be at least 18 years of age

Prescriber Restriction
Prescribed by a pulmonologist, a cardiologist, or a physician specializing in pulmonary arterial hypertension.

Coverage Duration
3 Months

Other Criteria
Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class IV patients OR 1.) Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class II-III who do not respond adequately to, are unable to tolerate, or are not candidates for one endothelin receptor antagonists (e.g. TRACLEER [bosentan] or LETAIRIS [ambrisentan]) and one phosphodiesterase-5 (PDE-5) inhibitors (e.g. REVATIO [sildenafil], ADCIRCA [tadalafil]).

Age Restriction
Patient must be at least 18 years of age.

Prescriber Restriction
Prescribed by a pulmonologist or a cardiologist

Coverage Duration
3 Months

Other Criteria
Medication is eligible for B vs. D determination

Indications
All FDA-approved Indications.

Off Label Uses
ORKAMBI (lumacaftor-ivacaftor)

Drugs
ORKAMBI ORAL TABLET

Exclusion Criteria
Use in combination with Kalydeco

Required Medical Information
The patient is positive for the F508del mutation on both alleles of the CFTR gene.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Otezla

Drugs
OTEZLA, OTEZLA STARTER ORAL TABLETS, DOSE PACK 10 MG (4)-20 MG (4)-30 MG (47)

Exclusion Criteria

Required Medical Information
Documented trial and failure of preferred TNF inhibitors (Enbrel and Humira) except for patients with oral ulcers associated with Behcet’s disease AND negative Tuberculin test prior to therapy AND patient is free of any clinically important active infections.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
OXANDROLONE

Drugs
oxandrolone oral tablet 10 mg, 2.5 mg

Exclusion Criteria
Pregnancy Category X

Required Medical Information
Statement indicating use to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, and to offset the protein catabolism associated with prolonged administration of corticosteroids. Statement indicating use for orphan drug indication, short stature associated with Turner syndrome, constitutional delay of growth and puberty, moderate or severe acute alcoholic hepatitis, Duchenne and Becker muscular dystrophy. Initial Therapy for AIDS Wasting: Diagnosis of AIDS wasting/cachexia. For treatment of anorexia associated with weight loss in patients with HIV: 1. Patient is receiving AIDS anti-retroviral therapy AND 2. experienced at least a. 7.5% unintentional weight loss over 6 months b. 10% unintentional weight loss over 12 months c. 5% body cell mass (BCM) loss within 6 months d. BMI less than 20 kg/m2 e. BCM less than 35% male (less than 23% female) and a BMI less than 27 kg/m2 AND 3. documentation of trial and failure, contraindication, or intolerance to megestrol at doses up to 800 mg daily.

Age Restriction

Prescriber Restriction

Coverage Duration
HIV Wasting: 3 months. All other indications: Through the Benefit Year

Other Criteria

Indications
All Medically-accepted Indications.

Off Label Uses
Drugs
OXBRYTA

Exclusion Criteria

Required Medical Information
Documentation that the patient has the diagnosis of sickle cell disease AND has experienced at least one sickle cell-related vaso-occlusive crisis within the past 12 months AND has a baseline hemoglobin range that is greater than or equal to 5.5 g/dL and less than or equal to 10.5 g/dL.

Age Restriction
Patient is 12 years of age or older.

Prescriber Restriction
Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease.

Coverage Duration
6 Months

Other Criteria
Continuation of therapy requires documentation of improved clinical benefit to therapy as demonstrated by increase in hemoglobin by 1 g/dL from baseline, decrease in the number of sickle cell-related vaso-occlusive crises, decrease in percent reticulocyte count from baseline, decrease in indirect bilirubin count from baseline, or physician attestation.

Indications
All FDA-approved Indications.

Off Label Uses
Oxervate (cenegermin)

Drugs
OXERVATE

Exclusion Criteria

Required Medical Information
Member has a diagnosis (documented in chart notes) of neurotrophic keratitis in the affected eye(s) AND Member is refractory to at least ONE conventional non-surgical treatment for neurotrophic keratitis (e.g. topical antibiotic eyedrops)

Age Restriction
Member is 2 years of age or older

Prescriber Restriction
The medication is prescribed by an ophthalmologist

Coverage Duration
8 weeks

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
**Exclusion Criteria**
Not to be used in combination with sapropterin dihydrochloride (Kuvan)

**Required Medical Information**
Documented Diagnosis of Phenylketonuria (PKU), AND blood phenylalanine concentration greater than 600 micromol/L, AND physician agrees to assess patient tolerability, blood phenylalanine concentration, AND prescriber and patient must be enrolled with the Palynziq REMS Program.

**Age Restriction**
18 years of age and older

**Prescriber Restriction**

**Coverage Duration**
3 Months

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
PANRETIN

Exclusion Criteria

Required Medical Information
Documented diagnosis of cutaneous lesions in members with AIDS-related Kaposi's sarcoma.

Age Restriction

Prescriber Restriction
Oncologist or HIV specialist

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
PCSK9

Drugs
PRALUENT PEN, REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

Exclusion Criteria

Required Medical Information
Clinical documentation (e.g., chart notes, laboratory values) required for initial authorization includes: 1. Documentation of one of the following diagnoses: A) Homozygous familial hypercholesterolemia (HoFH)(Repatha only), B) Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia), OR C) Atherosclerotic cardiovascular disease (ASCVD), AND 2. Documentation of any one of the following: a) Patient has been receiving statin therapy at a maximally tolerated dose and will continue to receive statin at maximally tolerated dose (maximally tolerated dose may include no statin therapy), b) Patient has a documented labeled contraindication to all statins, c) Patient has experienced rhabdomyolysis. Clinical documentation required for reauthorization includes: 1. Physician attestation of medication’s efficacy. For statin intolerant patients, we will cover pcsk9s without the member having to use statin therapy.

Age Restriction
HeFH, ASCVD: 18 years and older. HoFH: 13 years and older

Prescriber Restriction
Prescribed by or in consultation with or recommendation of, a Cardiologist, Endocrinologist, Lipid specialist

Coverage Duration
Initial Authorization will be for 6 months. Reauthorization will be for 1 year

Other Criteria
Other Criteria: A) HoFH: Patient meets one of the following: a) Patient has genetic confirmation of two mutant alleles at LDLR, APOB, PCSK9 or LDLRAP1 gene locus OR b) Patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) OR c) Patient has a treated LDL-C level greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha, Kynamro, or Juxtapid) OR d) Patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma B) Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia): The patient has a low-density lipoprotein cholesterol (LDL-C level) greater than or equal to 100 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy. C) ASCVD: The patient has a low-density lipoprotein cholesterol (LDL-C) greater than or equal to 70 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy. ASCVD diagnosis is confirmed by one of the following: acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin.

Indications
All FDA-approved Indications.

Off Label Uses
PEGASYS (peginterferon alfa-2a)

Drugs
PEGASYS PROCLICK SUBCUTANEOUS PEN INJECTOR 180 MCG/0.5 ML, PEGASYS SUBCUTANEOUS SOLUTION, PEGASYS SUBCUTANEOUS SYRINGE

Exclusion Criteria
Decompensated cirrhosis (Child Turcotte Pugh class B or C)

Required Medical Information
Diagnosis supporting covered indication. Criteria will be applied consistent with current AASLD-IDSA guidance.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Perseris (risperidone)

Drugs
PERSERIS

Exclusion Criteria

Required Medical Information
Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

Age Restriction

Prescriber Restriction

Coverage Duration
Through the benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Piqray (alpelisib)

Drugs
PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X 1-50 MG X 1), 300 MG/DAY (150 MG X 2)

Exclusion Criteria

Required Medical Information
Documentation that the patient is a postmenopausal female or a male AND has advanced or metastatic breast cancer
AND has HR-positive disease AND has HER2-negative disease AND has PIK3CA-mutated breast cancer as detected by a FDA approved test AND has progressed on or after at least one prior endocrine-based regimen AND the medication will be used in combination with fulvestrant.

Age Restriction

Prescriber Restriction
Oncologist

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
POMALYST

Exclusion Criteria

Required Medical Information
Patient has a diagnosis of multiple myeloma and the patient has received two prior therapies, including Revlimid and Velcade unless the patient has a contraindication or intolerance to Revlimid or Velcade and the patient has demonstrated disease progression on or within 60 days of completion of last therapy.

Age Restriction

Prescriber Restriction

Coverage Duration
3 Months

Other Criteria
Prescriber, pharmacist, and patient must be enrolled in the Pomalyst REMS program.

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Relapsed/refractory chronic immune (idiopathic) thrombocytopenic purpura (ITP) for greater than 6 months AND Baseline platelet count is less than 50,000/mcL AND Degree of thrombocytopenia and clinical condition increase the risk of bleeding AND Patient had an insufficient response, intolerance, contraindication to corticosteroids or immune globulin or inadequate response or contraindication to splenectomy, or B) Chronic hepatitis C and patient has thrombocytopenia defined as platelets less than 90,000/mcL for initiation (pre-treatment) of interferon therapy, or C) Severe aplastic anemia.

Age Restriction

Prescriber Restriction

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of cystic fibrosis.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
Pulmozyme should be used in conjunction with standard therapies for CF. For renewal, Patient is benefiting from treatment (i.e. improvement in lung function [FEV1], decreased number of pulmonary exacerbations).

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documentation of acute lymphoblastic leukemia (ALL) AND medication will be used as a component of a combination maintenance therapy regimen.

Age Restriction

Prescriber Restriction

Coverage Duration
Through benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
quinine sulfate

Exclusion Criteria
Treatment of nocturnal leg cramps

Required Medical Information
Documented diagnosis of Plasmodium falciparum malaria

Age Restriction

Prescriber Restriction

Coverage Duration
For malaria the authorization is for 7 days. For babesiosis the authorization is 10 days.

Other Criteria

Indications
All Medically-accepted Indications.

Off Label Uses
Drugs
RAVICTI

Exclusion Criteria
Acute hyperammonemia. N-acetylglutamate synthase (NAGS) deficiency

Required Medical Information
Diagnosis of urea cycle disorder involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamoylase (OTC), or argininosuccinic acid synthetase (AAS) confirmed via enzymatic, biochemical, or genetic testing AND patient has tried and had an inadequate response, is intolerant, or has a contraindication to Buphenyl for at least 3 months.

Age Restriction

Prescriber Restriction

Coverage Duration
Through benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Pregnancy (category X)

Required Medical Information
Diagnosis of one of the following: A) Multiple myeloma used in combination with dexamethasone, or B) Diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, or C) Mantle cell lymphoma and patient's disease has relapsed or progressed after trying at least two prior therapies (Velcade and one of the following: bendamustine, cladribine, fludarabine, rituximab), or D) previously treated follicular lymphoma and the medication will be used in combination with rituximab, or E) previously treated marginal zone lymphoma and the medication will be used in combination with rituximab AND patient is enrolled in the Revlimid REMS Program.

Age Restriction
18 years and older

Prescriber Restriction
Hematologist/oncologist. Registered in Revlimid REMS.

Coverage Duration
3 Months

Other Criteria
Indications
All FDA-approved Indications.

Off Label Uses
Drugs
RISPERDAL CONSTA INTRAMUSCULAR SUSPENSION, EXTENDED REL RECON 12.5 MG/2 ML, 25 MG/2 ML, 37.5 MG/2 ML, 50 MG/2 ML

Exclusion Criteria

Required Medical Information
Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documentation of: A) metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive OR B) solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation AND are metastatic or where surgical resection is likely to result in severe morbidity AND have either progressed following treatment or have no satisfactory alternative therapy.

Age Restriction
12 years of age or older

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
RUBRACA

Exclusion Criteria

Required Medical Information
Documented diagnosis of: 1) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer that had a complete or partial response to platinum-based chemotherapy OR 2) Deleterious BRCA mutation-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer that has been treated with two or more chemotherapies.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documentation of: 1) Newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive, as detected by a FDA approved test and will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation OR 2) Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
SABRIL, vigabatrin

Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Refractory complex partial seizures (CPS) AND has previously tried and failed two medications for the diagnosis of refractory complex partial seizures (i.e. carbamazepine, ethosuximide, felbamate, fosphenytoin, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, pregabalin, primidone, tiagabine, topiramate, valproic acid, divalproex sodium, zonisamide), or B) Infantile spasms (IS)

Age Restriction
10 years and older for CPS diagnosis. Children aged 1 month to 2 years old for IS.

Prescriber Restriction
Neurologist registered with the Vigabatrin REMS program

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Samsca not approved as an intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms. Samsca should not be initiated or re-initiated outside of a hospital setting.

Required Medical Information
Serum sodium levels. Initial therapy for hyponatremia (hypervolemic and euvolemic): 1. Diagnosis of significant hyponatremia (euvolemic or hypervolemic), AND 2. Treatment has been initiated or re-initiated in a hospital setting prior to discharge. Reauthorization for hypervolemic and euvolemic hyponatremia: 1. Documentation of clinical benefit, AND 2. Treatment has been initiated or re-initiated in a hospital setting prior to discharge.

Age Restriction

Prescriber Restriction

Coverage Duration
1 month

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
SECUADO

Exclusion Criteria

Required Medical Information
Diagnosis of Schizophrenia AND documented treatment failure or intolerable side effects from treatment with two formulary antipsychotic medications such as risperidone, ziprasidone, aripiprazole, olanzapine, and quetiapine.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of plan year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
SEROSTIM SUBCUTANEOUS RECON SOLN 4 MG, 5 MG, 6 MG

Exclusion Criteria
Acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure. Active malignancy. Active proliferative or severe non-proliferative diabetic retinopathy.

Required Medical Information
Diagnosis of AIDS-wasting syndrome or cachexia (defined as unintentional weight loss of at least 10% of baseline weight) AND Treatment failure with or intolerance to dronabinol or megestrol AND Patient is currently receiving treatment with antiretrovirals.

Age Restriction

Prescriber Restriction

Coverage Duration
3 months initial, renewable every 6 months

Other Criteria
For renewal, patient has experienced an increase in body weight and/or improvement in lead body mass AND wasting is still evident.

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
SIGNIFOR

Exclusion Criteria

Required Medical Information
Documentation of Cushing’s Disease diagnosis AND pituitary surgery is not an option or has not been curative

Age Restriction

Prescriber Restriction

Coverage Duration
Through benefit year

Other Criteria
For renewal, patient had a clinically meaningful reduction in 24-hour urinary free cortisol levels and/or improvement in signs or symptoms of the disease

Indications
All FDA-approved Indications.

Off Label Uses
**SILDENAFIL 20 MG (REVATIO)**

**Drugs**
*sildenafil (pulm.hypertension) oral tablet*

**Exclusion Criteria**
Should not be used in combination with organic nitrates. This product is only indicated for Pulmonary Hypertension and is not to be used for Erectile Dysfunction.

**Required Medical Information**
Statement of FDA approved diagnosis of pulmonary arterial hypertension

**Age Restriction**
18 years and older

**Prescriber Restriction**
Cardiologist or Pulmonologist

**Coverage Duration**
Through end of benefit year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria
Bedaquiline should not be used for latent, extrapulmonary (eg, CNS), or drug-sensitive TB, or non-TB mycobacteria.

Required Medical Information
 Diagnosis of pulmonary multidrug-resistant tuberculosis (MDR-TB). Bedaquiline should only be used in combination with at least 3 other drugs to which the patient's MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, treatment may be initiated with bedaquiline in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible. Isolates from patients who fail to convert or relapse following treatment should be tested for bedaquiline minimum inhibitory concentrations.

Age Restriction
18 years and older

Prescriber Restriction

Coverage Duration
24 weeks

Other Criteria
Use for more than 24 weeks should be evaluated on a case-by-case basis. Bedaquiline should be administered by directly observed therapy (DOT). Throughout treatment with, and following the last dose, patients should continue to take their companion drugs as directed.

Indications
All FDA-approved Indications.

Off Label Uses
Sofosbuvir/Velpatasvir

Drugs
sofosbuvir-velpatasvir

Exclusion Criteria

Required Medical Information
Provider must submit medical records documenting the following: 1) medical diagnosis of Chronic Hepatitis C with labs documenting genotype and subtype, AND 2) medical records documenting viral load taken within 6 months of beginning therapy

Age Restriction
18 years of age and older

Prescriber Restriction
Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician.

Coverage Duration
12 weeks or as defined by current AASLD/IDSA guidance

Other Criteria
Criteria and coverage durations will be applied consistent with current AASLD/IDSA guidance.

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of A) acromegaly AND Inadequate response to surgery and/or radiation therapy or patient cannot be treated with surgery and/or radiotherapy, or B) unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs), or C) carcinoid syndrome.

Age Restriction
18 years of age and older

Prescriber Restriction

Coverage Duration
3 months initial. Continuation 6 months if no progression

Other Criteria
For renewal, patient’s IGF-1 levels has normalized or improved.

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, or B) Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML AND failure, resistance, or intolerance to imatinib, or C) Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) with resistance or intolerance to imatinib, or D) Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase for pediatric patients.

Age Restriction

Prescriber Restriction
Prescriber must be an oncologist.

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
STELARA SUBCUTANEOUS

Exclusion Criteria

Required Medical Information
Diagnosis of 1 of the following: A) Mod-severe Crohn disease and trial of 2 or more of the following: corticosteroids (e.g., prednisone, methylprednisolone) or non-biologic DMARDs (e.g., azathioprine, MTX, mercaptopurine) AND trial of Humira, or B) Psoriatic arthritis and trial and failure of MTX, Humira, Enbrel, Xeljanz, Cosentyx, and Otezla, or C) Mod-severe chronic plaque psoriasis (affecting more than 5% of body surface area or crucial body areas such as the hands, feet, face, or genitals) and trial of at least 1 of the following: phototherapy (including but not limited to Ultraviolet A with a psoralen [PUVA] and/or retinoids [RePUVA] for at least 1 month or 1 or more oral systemic treatments (e.g., MTX, cyclosporine, acitretin, sulfasalazine) for at least 3 months AND trial and failure of Humira, Enbrel, Cosentyx, and Otezla.

Age Restriction
12 years and older for Psoriasis and 18 years of age and older for all other indications

Prescriber Restriction
Gastroenterologist for Crohn disease diagnosis

Coverage Duration
6 months

Other Criteria
Negative Tuberculin test prior to therapy AND patient is free of any clinically important active infections

Indications
All FDA-approved Indications.

Off Label Uses

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185
Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Metastatic colorectal cancer AND patient has previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based therapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if KRAS wild type, an anti-epidermal growth factor receptor (EGFR) therapy, or B) Gastrointestinal stromal tumors that is locally advanced, unresectable or metastatic and patient has tried and had an inadequate response, contraindication or intolerance to Gleevec or Sutent, or C) Hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib.

Age Restriction
18 years and older

Prescriber Restriction
Oncologist

Coverage Duration
3 Months

Other Criteria
Hepatic function will be monitored prior to and during treatment and, if patient has elevated liver function tests of hepatocellular necrosis, therapy will be interrupted and then reduced or discontinued.

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of congenital sucrose-isomaltase deficiency confirmed by: 1) Duodenal biopsy showing low sucrose activity and normal amounts of other disaccharides OR 2) Stool pH less than 6, increase in breath hydrogen of greater than 10ppm when challenged with sucrose after fasting, and negative lactose breath test.

Age Restriction

Prescriber Restriction
Prescribed by a gastroenterologist, endocrinologist, or genetic specialist

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

**Required Medical Information**
Clinical documentation of narcolepsy or obstructive sleep apnea AND failed at least TWO alternatives (e.g. methylphenidate, dextroamphetamine, modafinil and armodafinil).

Age Restriction

Prescriber Restriction

Coverage Duration
Through the plan year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Combination use with other kinase inhibitors (for example, sorafenib, etc).

Required Medical Information
Diagnosis of one of the following: A) Advanced/metastatic renal cell carcinoma, or B) Gastrointestinal stromal tumors after disease progression on or intolerance to Gleevec, or C) Progressive, well-differentiated pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease.

Age Restriction
Patient must be at least 18 years of age.

Prescriber Restriction
Must be prescribed by oncologist

Coverage Duration
3 months initial, then renewable in 6 month increments

Other Criteria
Indications
All FDA-approved Indications.

Off Label Uses
Drugs
SYLATRON SUBCUTANEOUS KIT 200 MCG, 300 MCG

Exclusion Criteria
Autoimmune hepatitis. Hepatic decompensation (Child-Pugh score greater than 6 [Class B or C])

Required Medical Information
Stated diagnosis from oncologist of treatment needed for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.

Age Restriction

Prescriber Restriction
Oncologist

Coverage Duration
3 months

Other Criteria
Medication is eligible for B vs. D determination

Indications
All FDA-approved Indications.

Off Label Uses
Sympazan (Clobazam)

Drugs
SYMPAZAN

Exclusion Criteria

Required Medical Information
Diagnosis of Lennox-Gastaut syndrome AND is being used as adjunctive therapy AND rationale for requiring oral film formulation.

Age Restriction
2 years and older

Prescriber Restriction
Prescribed by or in consultation with a neurologist.

Coverage Duration
Initial: 3 months, Renewal: through end of benefit year w/ stable disease

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of chronic myelogenous leukemia (CML) AND patient has tried and failed or has a contraindication or intolerance to two prior tyrosine kinase inhibitor therapies [eg, Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib), Bosulif (bosutinib)].

Age Restriction
18 years of age or older

Prescriber Restriction
Prescribed by a hematologist and/or oncologist

Coverage Duration
3 Months

Other Criteria
Medication is eligible for B vs. D determination

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
TAFINLAR ORAL CAPSULE 50 MG, 75 MG

Exclusion Criteria

Required Medical Information
Diagnosis of unresectable or metastatic melanoma along with BRAF V600E or BRAF V600K mutation status as detected by a US Food and Drug Administration-approved test.

Age Restriction
18 years or older

Prescriber Restriction
Oncologist

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documented diagnosis of: 1) metastatic non-small cell lung cancer (NSCLC) with tumors that have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test OR 2) metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, with disease progression on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documentation of deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.

Age Restriction

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs

*erlotinib, TARCEVA*

Exclusion Criteria

**Required Medical Information**
Diagnosis of one of the following: A) Locally advanced, unresectable, or metastatic pancreatic cancer and erlotinib will be used in combination with gemcitabine, or B) First-line treatment of metastatic non-small cell lung cancer in which tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an Food and Drug Administration (FDA)-approved test, or C) Maintenance treatment of locally advanced or metastatic non-small cell lung cancer when disease has not progressed after 4 cycles of platinum-based first-line chemotherapy, or D) Treatment of locally advanced or metastatic non-small cell lung cancer after failure of at least 1 prior chemotherapy regimen.

**Age Restriction**
18 years or older

**Prescriber Restriction**
Prescriber must be an oncologist.

**Coverage Duration**
Through end of benefit year

**Other Criteria**

**Indications**

**Off Label Uses**
Drugs
TASIGNA

Exclusion Criteria
Long QT syndrome. Uncorrected hypokalemia. Uncorrected hypomagnesemia. Concomitant use with a drug known to prolong the QT interval or strong cytochrome P450 3A4 inhibitors.

Required Medical Information
Diagnosis of one of the following: A) Newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase, or B) Ph+ chronic or accelerated phase chronic myeloid leukemia (CML) in adult patients resistant to or intolerant to prior therapy that included imatinib, or C) Ph+ chronic phase chronic myeloid leukemia (CML) in pediatric patients resistant to or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.

Age Restriction

Prescriber Restriction
Must be prescribed by Oncologist

Coverage Duration
Initial: 3 months, Renewal: 6 months with documentation of continued benefit

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
**Drugs**
**TAVALISSE**

**Exclusion Criteria**

**Required Medical Information**
Documented Platelet count less than $30 \times 10^9 / \text{L}$ and member had an insufficient response to previous treatment (corticosteroids, immunoglobulins, splenectomy, and/or a thrombopoietin receptor agonists).

**Age Restriction**
18 years or older

**Prescriber Restriction**
Hematologist

**Coverage Duration**
Initial Authorization will be for 3 months. Reauthorization will be for 1 year.

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria

Required Medical Information
Documentation of metastatic or locally advanced epithelioid sarcoma that is not eligible for complete resection.

Age Restriction

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
TECFIDERA ORAL CAPSULE, DELAYED RELEASE (DR/EC) 120 MG, 120 MG (14)-240 MG (46), 240 MG

Exclusion Criteria
Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

Required Medical Information
Diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting MS or progressive-relapsing MS, or secondary-progressive MS) OR patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documentation of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
THALOMID

Exclusion Criteria
Pregnancy (category X)

Required Medical Information
Diagnosis of one of the following: A) Multiple myeloma that is newly diagnosed and is receiving concurrent dexamethasone, or B) Acute treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL) AND the medication will not be used as monotherapy if the member has moderate to severe neuritis, or C) Maintenance therapy for prevention and suppression of cutaneous manifestations of ENL recurrence.

Age Restriction
12 years of age and older

Prescriber Restriction
Candidates must follow Thalomid REMS program requirements. Provider and pharmacy must be registered with this program.

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Tibsovo (Ivosidenib)

Drugs
TIBSOVO

Exclusion Criteria

Required Medical Information
Documentation of A) relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test OR B) newly-diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation and the patient is greater than or equal to 75 years old or has comorbidities that preclude use of intensive induction chemotherapy.

Age Restriction

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
TOBI PODHALER (tobramycin inhalation capsule)

Exclusion Criteria

Required Medical Information
Documented diagnosis of cystic fibrosis with Pseudomonas aeruginosa.

Age Restriction
6 years and older

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria
Patient must have contraindication/intolerance to or failure of tobramycin nebulizer solution (generic)

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documented trial, contraindication, or intolerance to diclofenac 1% topical gel and one oral NSAID (i.e. ibuprofen, naproxen, or meloxicam).

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Topical Retinoid

Drugs
\textit{tazarotene, TAZORAC, tretinoin}

Exclusion Criteria
Should not be used for photoaging/wrinkles

Required Medical Information
Statement of FDA approved diagnosis

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Tracleer

Drugs
bosentan, TRACLEER

Exclusion Criteria
Receiving concomitant cyclosporine A or glyburide therapy. Aminotransferase elevations are accompanied by signs or symptoms of liver dysfunction or injury or increases in bilirubin at least 2 times the upper limit of normal. For female patients, pregnancy must be excluded prior to the start of therapy and will be prevented thereafter with reliable contraception.

Required Medical Information
Diagnosis of pulmonary arterial hypertension (PAH) WHO Group I AND New York Heart Association (NYHA) Functional Class II-IV, AND The patient has had a vasoreactivity test unless the provider indicates that the patient has a contraindication to the test or indicates clinical inappropriateness to the vasoreactivity test, AND Must have tried and failed or has a contraindication to the use of a calcium channel blocker if they have a positive vasoreactivity test, AND If the patient is an adult with functional class II or III, must have tried and failed or intolerant to sildenafil, or provide documentation as to why contraindicated to initiation of sildenafil.

Age Restriction
Greater or equal to 3 years of age

Prescriber Restriction
Available only to those enrolled in the Bosentan REMS program. Prescription is written by or in consultation with a pulmonologist, a cardiologist.

Coverage Duration
3 Months

Other Criteria
Liver aminotransferases will be measured prior to initiation of treatment and then monthly.

Indications
All FDA-approved Indications.

Off Label Uses
Trientine

Drugs
trientine

Exclusion Criteria

Required Medical Information
Documented diagnosis of Wilson's disease and the patient is intolerant of penicillamine.

Age Restriction

Prescriber Restriction

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Trikafta

Drugs
TRIKAFTA

Exclusion Criteria
Use in combination with other CFTR modulator (Orkambi, Kalydeco, or Symdeko)

Required Medical Information
Documentation of Cystic Fibrosis AND confirmation of presence of at least one F508del mutation in CFTR gene through genetic testing.

Age Restriction
12 years of age or older

Prescriber Restriction
Prescribed by pulmonologist or a physician who specializes in the treatment of Cystic fibrosis

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All Medically-accepted Indications.

Off Label Uses
Drugs
trimipramine

Exclusion Criteria

Required Medical Information
Diagnosis of depression and treatment failure of at least two other formulary medications used in the treatment of depression.

Age Restriction

Prescriber Restriction

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
DRUGS

TRINTELLIX

Exclusion Criteria

Required Medical Information
Diagnosis of major depressive disorder and treatment failure of at least two other formulary medications used in the treatment of major depressive disorder

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Documentation of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

Age Restriction

Prescriber Restriction
Oncologist

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND 1. the medication will be used in combination with Xeloda in a patient with advanced or metastatic disease and the patient has received prior therapy including an anthracycline, a taxane, and trastuzumab, or 2) The medication will be used in combination with Femara for the treatment of a postmenopausal woman with hormone receptor-positive metastatic disease for whom hormonal therapy is indicated.

Age Restriction
18 years or older

Prescriber Restriction
Must be prescribed by Oncologist and Oncologist must monitor treatment

Coverage Duration
Initial: 3 months, Renewal: 6 months with documentation of continued benefit

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Osteoporosis in a postmenopausal female AND one or more of the following: 1) History of osteoporotic fracture, or 2) Documented trial and failure of bisphosphonate or 3) Documented contraindication or intolerance to bisphosphonate therapy. Patient has not received more than 2 years of therapy with Tymlos.

Age Restriction

Prescriber Restriction

Coverage Duration
Initial: 1 year. Renewal: 1 year not to exceed 2 years of total

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
UPTRAVI ORAL TABLET, UPTRAVI ORAL TABLETS, DOSE PACK

Exclusion Criteria

Required Medical Information
Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class IV patients OR 1.) Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class II-III who do not respond adequately to, are unable to tolerate, or are not candidates for endothelin receptor antagonists (e.g. TRACLEER [bosentan] or LETAIRIS [ambrisentan]) and phosphodiesterase-5 (PDE-5) inhibitors (e.g. REVATIO [sildenafil], ADCIRCA [tadalafil]).

Age Restriction
Patient must be at least 18 years of age.

Prescriber Restriction
Prescribed by a pulmonologist or a cardiologist

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
VALCHLOR

Exclusion Criteria

Required Medical Information
Documented diagnosis of stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy.

Age Restriction

Prescriber Restriction

Coverage Duration
Through benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Vancomycin

Drugs
vancomycin oral capsule

Exclusion Criteria

Required Medical Information
Diagnosis of A) Clostridium difficile-associated diarrhea, AND Stool culture report within the previous 30 days indicating positive C. difficile toxin, or B) Staphylococcus aureus (including methicillin-resistant strains)enterocolitis

Age Restriction

Prescriber Restriction

Coverage Duration
14 days, Patients with multiple relapses: 6 weeks

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
VENCLEXTA (venetoclax)

**Drugs**
VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG, VENCLEXTA STARTING PACK

**Exclusion Criteria**

**Required Medical Information**
Documented diagnosis of A) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) or B) newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy and will be used in combination with azacitidine, decitabine, or low-dose cytarabine.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**
3 months

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria

**Required Medical Information**
Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class IV patients OR 1.) Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class II-III who do not respond adequately to, are unable to tolerate, or are not candidates for one endothelin receptor antagonists (e.g. TRACLEER [bosentan] or LETAIRIS [ambrisentan]) and one phosphodiesterase-5 (PDE-5) inhibitors (e.g. REVATIO [sildenafil], ADCIRCA [tadalafil]).

**Age Restriction**
18 years or older

**Prescriber Restriction**
Cardiologist or Pulmonologist

**Coverage Duration**
3 months initial, renewable every 6 months

**Other Criteria**
Ventavis is subject to Part B vs. Part D review.

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria

**Required Medical Information**
Refractory Schizophrenia/Schizoaffective Disorder: Versacloz will be approved upon receipt of physician statement that member requires the use of an atypical antipsychotic for the treatment of refractory schizophrenia that has failed to respond two courses of standard formulary antipsychotic agents or to reduce the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder AND is intolerant to oral solutions or unable to swallow other oral formulations. Formulary antipsychotics include: clozapine (tablet), risperidone (orally disintegrating tablet, tablet, solution), quetiapine (tablet), and olanzapine (tablet).

**Age Restriction**
18 years or older

**Prescriber Restriction**
Part of a clozapine registry

**Coverage Duration**
Through the benefit year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Verzenio

Drugs
VERZENIO

Exclusion Criteria

Required Medical Information
Documented diagnosis of one of the following: A) Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer AND the patient is postmenopausal AND the medication is used in combination with an aromatase inhibitor as initial endocrine-based therapy, or B) hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy AND being used in combination with fulvestrant, or C)as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

Age Restriction

Prescriber Restriction
Oncologist

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Exclusion Criteria
Documentation of gallbladder removal, known or suspected biliary duct obstruction, or a history of pancreatitis.

Required Medical Information
Diagnosis of irritable bowel syndrome with diarrhea and failed at least TWO alternatives from different classes such as antidiarrheals (e.g. loperamide), antispasmodics (e.g. dicyclomine).

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
VIIBRYD (vilazodone)

Drugs
VIIBRYD ORAL TABLET 10 MG, 20 MG, 40 MG, VIIBRYD ORAL TABLETS, DOSE PACK 10 MG (7)- 20 MG (23)

Exclusion Criteria

Required Medical Information
Documented trial of at least two generic antidepressants (e.g. bupropion, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, paroxetine CR, sertraline, duloxetine, venlafaxine).

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
VIMPAT

Drugs
VIMPAT ORAL SOLUTION, VIMPAT ORAL TABLET

Exclusion Criteria

Required Medical Information
Diagnosis of partial-onset seizures and treatment failure of at least two other formulary medications used in the treatment of partial-onset seizures.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
Max dose 400mg/day

Indications
All FDA-approved Indications.

Off Label Uses
Vitrakvi (larotrectinib)

Drugs
VITRAKVI ORAL CAPSULE 100 MG, 25 MG, VITRAKVI ORAL SOLUTION

Exclusion Criteria

Required Medical Information
Clinical documentation of unresectable or metastatic solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion and have no satisfactory alternative treatments or that have progressed following treatment.

Age Restriction

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Vizimpro (Dacomitinib)

Drugs
VIZIMPRO

Exclusion Criteria

Required Medical Information
Documentation that medication will be used for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

Age Restriction

Prescriber Restriction
Oncology

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
VORICONAZOLE

Drugs
voriconazole oral

Exclusion Criteria

Required Medical Information
Documentation of invasive aspergillosis, bronchopulmonary aspergillosis, candidemia and disseminated candidiasis in skin, abdomen, kidney, bladder wall and wounds, esophageal candidiasis, and serious Candida infections, infections caused by the emerging pathogens Scedosporium sp. and Fusarium sp., or rare and refractory fungal infections should be provided. Preferred alternative for Candida: oral fluconazole

Age Restriction
2 years or older

Prescriber Restriction

Coverage Duration
6 months

Other Criteria

Indications
All Medically-accepted Indications.

Off Label Uses
Exclusion Criteria

**Required Medical Information**
Diagnosis of one of the following: A) Advanced/metastatic renal cell carcinoma, or B) Advanced soft tissue sarcoma and patient received at least one prior chemotherapy (e.g., doxorubicin, dacarbazine, ifosfamide, epirubicin, gemcitabine, docetaxel, or vinorelbine).

**Age Restriction**
18 years of age and older

**Prescriber Restriction**
Oncologist

**Coverage Duration**
Initial: 3 months, Renewal: 6 months with documentation of continued benefit

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
VRAYLAR ORAL CAPSULE, VRAYLAR ORAL CAPSULE, DOSE PACK

Exclusion Criteria

Required Medical Information
Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

Age Restriction

Prescriber Restriction

Coverage Duration
Schizophrenia: Through end of benefit year, Bipolar disorder: 12 weeks

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Wakix (Pitolisant)

Drugs
WAKIX

Exclusion Criteria

Required Medical Information
Diagnosis of one of Excessive daytime sleepiness in patients with narcolepsy AND 1. Submission of sleep study with narcolepsy diagnosis, AND 2. currently NOT taking any sedative hypnotics or other CNS depressants AND 3. has experienced inadequate response or intolerable side effects to two preferred products (modafinil, armodofinil, methylphenidate, or dextroamphetamine).

Age Restriction

Prescriber Restriction

Coverage Duration
Initial: 3 months, Renewal: 6 months with documentation of continued benefit

Other Criteria
For renewal, the patient had a positive response to the medication (increased sleep quality for patients with narcolepsy).

Indications
All FDA-approved Indications.

Off Label Uses
**Exclusion Criteria**

**Required Medical Information**
Documented diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test.

**Age Restriction**
18 years and older

**Prescriber Restriction**
Oncologist

**Coverage Duration**
3 months

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
XATMEP

Exclusion Criteria

Required Medical Information
Clinical documentation of acute lymphoblastic leukemia (ALL) or polyarticular juvenile ideopathic arthritis (pJIA). For the diagnosis of pJIA, the member must have had an adequate trial and failure of a full dose NSAID (minimum 12 weeks).

Age Restriction
Must be under 18 years of age.

Prescriber Restriction
pJIA indications from Rheumatologist
All other indications from Oncologist

Coverage Duration
Through the end of the benefit year.

Other Criteria
Medication is eligible for B vs. D determination

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
XELJANZ, XELJANZ XR ORAL TABLET EXTENDED RELEASE 24 HR 11 MG, 22 MG

Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) Psoriatic Arthritis AND documented trial and failure of preferred TNF inhibitors (Enbrel and Humira) AND negative Tuberculin test prior to therapy AND patient is free of any clinically important active infections, or B) Rheumatoid Arthritis AND documented trial and failure of preferred TNF inhibitors (Enbrel and Humira) AND negative Tuberculin test prior to therapy AND patient is free of any clinically important active infections, or C) Ulcerative Colitis AND documented trial and failure of preferred TNF inhibitor (Humira) AND negative Tuberculin test prior to therapy AND patient is free of any clinically important active infections.

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
**Drugs**
**XENAZINE ORAL TABLET 12.5 MG, 25 MG**

**Exclusion Criteria**
Actively suicidal. Untreated or inadequately treated depression. Impaired hepatic function. Concomitant use of monoamine oxidase inhibitors. Concomitant use of reserpine or within 20 days of discontinuing reserpine.

**Required Medical Information**
Diagnosis of chorea associated with Huntington’s disease AND any medication possibly contributing to the underlying symptoms of chorea has been discontinued (e.g., antipsychotics, metoclopramide, amphetamines, methylphenidate, dopamine agonists, etc.) unless cessation would be detrimental to the underlying condition.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**
Initial Therapy: 3 months. Reauthorization: through end of benefit year

**Other Criteria**
Should not be used in patients who have inadequately treated depression, or patients who are actively suicidal.

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria
Hypocalcemia (calcium less than 8.0 mg/dL).

Required Medical Information
Diagnosis of one of the following: A) Multiple Myeloma and Bone Metastasis from solid tumors (e.g., breast cancer, castrate-resistant prostate cancer, thyroid carcinoma, kidney, or non-small cell lung cancer) and medication will be used for the prevention of skeletal-related events (e.g., spinal cord compression, hypercalcemia, bone pain or lesions requiring radiation or surgery), or B) Giant cell tumor of bone that is unresectable or surgical resection is likely to result in severe morbidity, or C) Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy (i.e. alendronate, ibandronate, risedronate).

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria
Medication is eligible for B vs. D determination

Indications
All FDA-approved Indications.

Off Label Uses
XIFAXAN

Drugs
XIFAXAN ORAL TABLET 200 MG

Exclusion Criteria
Allergy to rifamycin agents

Required Medical Information
Diagnosis of traveler's diarrhea and patient does not have fever or blood in the stool

Age Restriction
12 years of age or older

Prescriber Restriction

Coverage Duration
Traveler's diarrhea: 3 days

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
XIFAXAN ORAL TABLET 550 MG

Exclusion Criteria
Allergy to rifamycin agents

Required Medical Information
Diagnosis of hepatic encephalopathy and tried and failed lactulose therapy OR Diagnosis of irritable bowel syndrome with diarrhea and failed at least TWO alternatives from different classes such as antidiarrheals (e.g. loperamide), antispasmodics (e.g. dicyclomine).

Age Restriction
Hepatic encephalopathy and IBS-D: 18 years of age or older

Prescriber Restriction

Coverage Duration
Hepatic encephalopathy: through benefit year, IBS-D: 6 weeks

Other Criteria
Indications
All FDA-approved Indications.

Off Label Uses
Drugs
XOLAIR

Exclusion Criteria

Required Medical Information
Diagnosis of A) moderate to severe persistent allergic asthma AND Evidence of specific allergic sensitivity confirmed by positive skin test (i.e. prick/puncture test) or blood test (i.e. radioallergosorbent test) for a specific IgE or in vitro reactivity to a perennial aeroallergen AND Pretreatment serum IgE levels greater than 30 and less than 700 IU/mL for patients 12 years of age or older or greater than 30 and less than 1300 for patients 6 to 11 years of age AND Symptoms are not adequately controlled with at least ONE inhaled corticosteroid (ICS) plus long-acting beta2-agonist (LABA) (e.g. Advair, Symbicort) for at least 3 months unless patient is intolerant to such treatment or is contraindicated, or B) Treatment of chronic idiopathic urticaria in adults and adolescents 12 years and older who remain symptomatic despite H1 antihistamine treatment (i.e. loratidine, cetirizine, levocetirizine, fexofenadine, etc.).

Age Restriction
6 years of age or older

Prescriber Restriction
Initial drug order must be by an allergist/immunologist, dermatologist or a pulmonologist

Coverage Duration
6 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Xospata (gilteritinib)

Drugs
XOSPATA

Exclusion Criteria

**Required Medical Information**
Clinical documentation of relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

**Age Restriction**

**Prescriber Restriction**
Oncology

**Coverage Duration**
3 months

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
XPOVIO ORAL TABLET 100 MG/WEEK (20 MG X 5), 160 MG/WEEK (20 MG X 8), 60 MG/WEEK (20 MG X 3), 80 MG/WEEK (20 MG X 4)

Exclusion Criteria

Required Medical Information
Documentation that the medication will be used in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.

Age Restriction

Prescriber Restriction
Oncologist

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
XTANDI

Exclusion Criteria

Required Medical Information
Diagnosis of A) Metastatic castration-resistant prostate cancer AND the patient has tried and had an inadequate response, contraindication or intolerance to Zytiga OR B) Non- metastatic Castration-resistant prostate cancer (CRPC).

Age Restriction

Prescriber Restriction
Oncologist or urologist

Coverage Duration
3 Months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
**Exclusion Criteria**
Contraindications: Patient is being treated with sedative hypnotic agents, other CNS depressants, or using alcohol. Patient has succinic semialdehyde dehydrogenase deficiency.

**Required Medical Information**
Diagnosis of one of the following: A) Excessive daytime sleepiness in patients with narcolepsy AND 1. Submission of sleep study with narcolepsy diagnosis, AND 2. currently NOT taking any sedative hypnotics or other CNS depressants AND 3. has experienced inadequate response or intolerable side effects to two preferred products (modafinil, armodofinil, methylphenidate, or dextroamphetamine) AND 4. The requested dose does not exceed the FDA indicated maximum (9gm/night), or B) Cataplexy in patients with narcolepsy AND 1. Submission of sleep study showing narcolepsy diagnosis, AND 2. currently NOT taking any sedative hypnotics or other CNS depressants, AND 3. does not have sleep apnea, AND 4. The dose does not exceed the FDA indicated maximum (9gm/night).

**Age Restriction**
7 years of age or older

**Prescriber Restriction**

**Coverage Duration**
Initial: 3 months, Renewal: 6 months with documentation of continued benefit

**Other Criteria**
Patient and physician must adhere to all regulations of the Xyrem REMS Program. For renewal, the patient had a positive response to the medication (increased sleep quality for patients with narcolepsy).

**Indications**
All FDA-approved Indications.

**Off Label Uses**
**Exclusion Criteria**

**Required Medical Information**
Documented diagnosis of metastatic castration resistant prostate cancer (CRPC) AND the medication is being used in combination with methylprednisolone AND medication not being used as dual therapy with another androgen receptor inhibitor.

**Age Restriction**
18 years of age or older

**Prescriber Restriction**

**Coverage Duration**
3 Months

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
*miglustat, ZAVESCA*

Exclusion Criteria

**Required Medical Information**
Diagnosis of mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to constraints such as allergy, hypersensitivity, or poor venous access).

**Age Restriction**
18 years or older

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Exclusion Criteria

**Required Medical Information**
Documented diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in a complete or partial response to platinum-based chemotherapy

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**
Through end of benefit year

**Other Criteria**

**Indications**
All FDA-approved Indications.

**Off Label Uses**
Drugs
ZELBORAF

Exclusion Criteria
Combination use with ipilimumab

Required Medical Information
Diagnosis of A) unresectable or metastatic melanoma whose tumors express a gene mutation called BRAF V600E detected by an FDA approved test. Vemurafenib is not recommended for use in patients with wild-type BRAF melanoma. OR B) Erdheim-Chester Disease (ECD) with BRAF V600 mutation.

Age Restriction
18 years or older

Prescriber Restriction
Oncologist

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
zolpidem oral tablet

Exclusion Criteria

Required Medical Information
Documented trial and failure of two non high risk formulary alternatives

Age Restriction
PA applies to patients 65 years and older.

Prescriber Restriction

Coverage Duration
Through end of benefit year

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
ZYDELIG

Exclusion Criteria

Required Medical Information

Age Restriction

Prescriber Restriction

Coverage Duration
Through end of benefit year.

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
ZYKADIA ORAL TABLET

Exclusion Criteria

Required Medical Information
Documented diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test

Age Restriction

Prescriber Restriction

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
Drugs
abiraterone

Exclusion Criteria

Required Medical Information
Diagnosis of one of the following: A) metastatic prostate cancer AND Patient has castration-resistant disease (defined by tumor growth/disease progression, risk in PsA levels, new metastases) AND abiraterone will be used in combination with prednisone, or B) Metastatic high-risk castration-sensitive prostate cancer AND abiraterone will be used in combination with prednisone.

Age Restriction

Prescriber Restriction

Coverage Duration
3 months

Other Criteria

Indications
All FDA-approved Indications.

Off Label Uses
ZYVOX (linezolid)

Drugs
linezolid

Exclusion Criteria

Required Medical Information
Culture and sensitivity reports verifying: 1. VRE infections within past 30 days. 2. Nosocomial pneumonia (MRSA) within past 30 days. 3. Nosocomial or CAP (MSSA or S. pneumoniae) within past 30 days and failure/resistance to 2 preferred antibiotics. 4. Complicated SSI without osteomyelitis (MRSA) within past 30 days. 5. Uncomplicated SSI (MRSA) within past 30 days or empirical treatment of uncomplicated or community-acquired complicated SSI without osteomyelitis (MRSA likely) and failure/resistance to 2 preferred antibiotics. 6. Uncomplicated or complicated SSI without osteomyelitis (MSSA, S. pyogenes, or S. agalactiae (complicated SSI only)) within past 30 days and failure/resistance to 2 preferred antibiotics.

Age Restriction

Prescriber Restriction
Prescribing physician must be an infectious disease specialist

Coverage Duration
Non-MRSA nosocomial or community acquired pneumonia, SSI: 14 days Other uses: 28 days

Other Criteria
Nosocomial or community acquired pneumonia (MSSA or S. pneumoniae) preferred antibiotics: Amoxicillin/Clavulanate, Azithromycin, Cephalexin, Clarithromycin, Levaquin. Uncomplicated SSI (MRSA) or empirical treatment of patients with uncomplicated or community-acquired complicated SSI without osteomyelitis (MRSA likely) preferred antibiotics: Trimethoprim/sulfamethoxazole, Tetracycline, Doxycycline, Minocycline, Clindamycin. Uncomplicated or complicated SSI without osteomyelitis (MSSA, S. pyogenes, or S. agalactiae (complicated SSI only)) preferred antibiotics: Amoxicillin/clavulanate, Cephalexin, Ciprofloxacin, Clindamycin, Levaquin, Trimethoprim/Sulfamethoxazole, Dicloxacillin.

Indications
All FDA-approved Indications.

Off Label Uses
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For more recent information or other questions, please contact Health First Health Plans Customer Service at 1.855.882.6467 or, for TTY users, 1.800.955.8771, weekdays from 8 a.m. to 8 p.m. and Saturdays from 8 a.m. to noon. From October 1 through March 31, we are available seven days a week from 8 a.m. to 8 p.m. or visit myAHplan.com.

Customer Service has language interpreter services available for non-English speakers at no cost.

This information is also available at no cost in other formats. By contacting Customer Service you may request your materials be read aloud, emailed, or mailed in large print.

You must generally use network pharmacies to use your prescription drug benefit. Benefits, formulary, pharmacy network, premium and/or copayments/coinsurance may change on January 1, 2021, and from time to time during the year.

Advent Health Advantage Plans is administered by Health First Health plans. Health First Health Plans is an HMO plan with a Medicare contract. Enrollment in Health First Health Plans depends on contract renewal.

The Formulary, pharmacy network, may change at any time. You will receive notice when necessary.
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AdventHealth Advantage Plans:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, accessible electronic formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, please contact our Civil Rights Coordinator.

If you believe that AdventHealth Advantage Plans has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: Civil Rights Coordinator, 6450 US Highway 1, Rockledge, FL 32955, 321-434-4521, 1-800-955-8771 (TTY), Fax: 321-434-4362, civilrightscoordinator@hf.org. You can file a grievance in person or by mail, fax or email. If you need help filing a grievance our Civil Rights Coordinator, is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD).


AdventHealth Advantage Plans is administered by Health First Health Plans. Health First Health Plans is an HMO plan with a Medicare contract. Enrollment in Health First Health Plans depends on contract renewal.
ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1-855-882-6467 (TTY: 1-800-955-8771).


Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-855-882-6467（TTY：1-800-955-8771）。


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