



6450 U.S. Highway 1  
Rockledge, FL 32955  
myHFHP.org

## **Medicare Advantage Plans**

### **2020 Prior Authorization (PA)**

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

Y0089\_MPINFO7903\_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**

**Drugs**  
**ADEMPAS****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)

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### **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**

**Drugs**

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

**Exclusion Criteria**

**Required Medical Information**

diagnosis of A) anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)who have progressed on or are intolerant to crizotinib OR B) tyrosine kinase inhibitor-naïve advanced anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC).

**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**

**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**

Acquired Aplastic Anemia: 1. History of failure to erythropoietic stimulating agent, OR 2. Used in combination with antilymphocyte globulin or both antilymphocyte globulin and corticosteroid treatment. Hypoplastic Anemia: 1. Diagnosis of hypoplastic anemia due to myelotoxic drugs, AND 2. Failure to erythropoietic stimulating agent. Pure Red Cell Aplasia: Failure of immunosuppressive therapy. Anemia of Chronic Renal Failure: Failure to an erythropoietic stimulating agent. Preferred Erythropoietin Stimulating Agent: Procrit. Tablet should not replace correcting iron, folic acid, and vitamin B12.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## APOKYN

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### **Drugs** **APOKYN**

#### **Exclusion Criteria**

Use with 5HT3-antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron).

#### **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**

**Drugs**  
**APTIOM**

**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**

**Drugs**  
**ARCALYST**

**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**

**Drugs**  
**AUBAGIO**

**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**

**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**

**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**



**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**

**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**

**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, Rituxan, Stelara, Cimzia, Kineret, Amevive, Orencia, 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 auto-antibody 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**

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### **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**

**Drugs****BETASERON SUBCUTANEOUS 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**

## BOSULIF

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### 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

**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**



**Drugs**

**ABILIFY MAINTENA, 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**

## BRIVIACT (brivaracetam)

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### Drugs

BRIVIACT ORAL SOLUTION, BRIVIACT ORAL TABLET 10 MG, 100 MG, 25 MG, 50 MG, 75 MG

### 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

**Drugs**  
**BRUKINSA**

**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**

## BUPHENYL

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### **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

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### Drugs

*butalbital-acetaminop-caf-cod oral capsule 50-325-40-30 mg, butalbital-acetaminophen oral tablet 50-325 mg, butalbital-acetaminophen-caff oral capsule 50-325-40 mg, butalbital-acetaminophen-caff oral tablet 50-325-40 mg, butalbital-aspirin-cafeine oral capsule, **TENCON ORAL TABLET 50-325 MG, VTOL LQ***

### 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)**

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### **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 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



**Drugs**  
**CALQUENCE**

**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**

## CANCIDAS

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### 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

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### 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

**CARBAGLU**

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**Drugs**  
**CARBAGLU**

**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**

**Drugs**  
**CAYSTON**

**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**

**Drugs**  
**CINRYZE****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 X1-20 MG X1), 140 MG/DAY(80 MG X1-20 MG X3), 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**



## COPAXONE

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### 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**

**Drugs**  
**CORLANOR**

**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**

**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**

## CYCLOSET

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### **Drugs** **CYCLOSET**

#### **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**

## CYSTAGON

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### 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



**Drugs**  
**CYSTARAN**

**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 old 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**

**Drugs**

**DOPTELET (10 TAB PACK), DOPTELET (15 TAB PACK), DOPTELET (30 TAB PACK)**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of A)Chronic liver disease, AND has thrombocytopenia with platelet count less than  $50 \times 10^9/L$ , 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**

### **Drugs**

*dronabinol*, **MARINOL**

### **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**

**Drugs**

**DUPIXENT PEN, DUPIXENT SYRINGE 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**

patients 6 years of age and older for atopic dermatitis, 12 years of age and older for asthma, and adults for chronic rhinosinusitis with nasal polyposis.

**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**  
**EGRIFTA SV**

**Exclusion Criteria**

**Required Medical Information**  
Diagnosis of HIV associated lipodystrophy

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**  
Through end of benefit year

**Other Criteria**

**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**

**Drugs**

**ENBREL MINI, ENBREL SUBCUTANEOUS RECON SOLN, ENBREL SUBCUTANEOUS SOLUTION, ENBREL SUBCUTANEOUS SYRINGE 25 MG/0.5 ML (0.5), 50 MG/ML (1 ML), ENBREL SURECLICK**

**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 at least two NSAIDs, 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 to at least two of the following: phototherapy (including but not limited to Ultraviolet A with a psoralen [PUVA] and/or retinoids [RePUVA] for at least one continuous month or one or more oral systemic treatments (i.e. methotrexate, cyclosporine, acitretin, sulfasalazine) for at least 3 months.

**Age Restriction**

2 years of age or older for JIA. 4 years of age or older for plaque psoriasis. 18 years of age or older for all other indications.

**Prescriber Restriction****Coverage Duration**

Through end of benefit year

**Other Criteria**

Preferred NSAIDs include: ibuprofen, naproxen, ketoprofen, meloxicam. 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**

**Drugs**  
**ENSPRYNG**

**Exclusion Criteria**

**Required Medical Information**  
Requires diagnosis of Neuromyelitis optica spectrum disorder

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**  
Through end of benefit year

**Other Criteria**

**Indications**  
All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**EPIDIOLEX**

**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**

**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**

**Drugs**  
**ERIVEDGE**

**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**  
**EVRYSDI**

**Exclusion Criteria**

**Required Medical Information**  
Diagnosis of spinal muscular atrophy.

**Age Restriction**  
Patients 2 months and older

**Prescriber Restriction**

**Coverage Duration**  
Through end of benefit year

**Other Criteria**

**Indications**  
All FDA-approved Indications.

**Off Label Uses**

**Drugs**

*deferasirox oral tablet, dispersible*, **EXJADE**

**Exclusion Criteria**

Creatinine clearance less than 40 mL/minute. Platelet count less than 50 x 10<sup>9</sup>/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**

## FANAPT (iloperidone)

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### Drugs

FANAPT ORAL TABLET, FANAPT ORAL TABLETS,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

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/ $\mu$ L within previous 12 months or greater than or equal to 150 cells/ $\mu$ L 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**



**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**

**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  $1.5 \times 10^9/L$ .

**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  $0.5 \times 10^9/L$

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**FETZIMA**

**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**  
**FINTEPLA**

**Exclusion Criteria**

**Required Medical Information**

Patients had a clinical diagnosis of Dravet syndrome and seizures that were inadequately controlled on at least 1 antiepileptic drug (AED) OR treatment including vagal nerve stimulation OR ketogenic diet.

**Age Restriction**

Children 2 and older

**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**

**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**  
**GAVRETO**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of Non-small cell lung cancer, metastatic, RET fusion-positive.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**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 Ia 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**  
**GILOTRIF****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**

**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**

**Drugs**  
**HETLIOZ**

**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**



### Drugs

*clemastine oral tablet 2.68 mg, cyproheptadine oral tablet, hydroxyzine HCl oral solution 10 mg/5 mL, 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**

**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

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**

*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

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### 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

## HRM - SULFONYLUREAS

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### 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**

**Drugs**

**HUMIRA PEN, HUMIRA PEN CROHNS-UC-HS START, HUMIRA PEN PSOR-UEVITS-ADOL HS, HUMIRA SUBCUTANEOUS SYRINGE KIT 10 MG/0.2 ML, 20 MG/0.4 ML, 40 MG/0.8 ML, HUMIRA(CF) PEN CROHNS-UC-HS, HUMIRA(CF) PEN PSOR-UV-ADOL HS, HUMIRA(CF) PEN SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML, HUMIRA(CF) SUBCUTANEOUS SYRINGE KIT 10 MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML**

**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. mesalamine, 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**

**Drugs**  
**IBRANCE****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**

**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**

**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**

**Drugs**  
**INCRELEX****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**  
**INQOVI**

**Exclusion Criteria**

**Required Medical Information**

Required diagnosis of Myelodysplastic syndrome, Previously treated and untreated, de novo and secondary, with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups)

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**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**

**Drugs****INTRON A INJECTION RECON SOLN 18 MILLION UNIT (1 ML), 50 MILLION UNIT (1 ML)****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 Kaposi 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.

**Off Label Uses**



**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**

**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

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### **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**

**Drugs**  
**JAKAFI**

**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 thrombocythemiamyelofibrosis 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  $50 \times 10^9/L$  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 ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG****Exclusion Criteria**

Pregnancy. Concomitant administration of moderate or strong CYP3A4 inhibitors (e.g., clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/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 tendinous 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**  
**KESIMPTA PEN**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of relapsing forms of multiple sclerosis (clinically isolated syndrome, relapsing-remitting MS, progressive-relapsing MS, or secondary-progressive MS)

**Age Restriction**

**Prescriber Restriction**

**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**

**Drugs**  
**KORLYM****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 Cushing's 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 Cushing's 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**

**Drugs**

**KOSELUGO ORAL CAPSULE 10 MG, 25 MG**

**Exclusion Criteria**

**Required Medical Information**

Documentation that the member has neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

**Age Restriction**

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**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**

## Kynmobi (apomorphine)

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### Drugs

KYNMOBI SUBLINGUAL FILM 10 MG, 15 MG, 20 MG, 25 MG, 30 MG

### Exclusion Criteria

#### Required Medical Information

Requires diagnosis of Parkinson's disease

### 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

**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 X2), 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**

**Drugs****LEUKINE INJECTION RECON SOLN****Exclusion Criteria**

Chemotherapy or radiotherapy within 24 hours or concomitantly, excess leukemic myeloid blasts in the bone marrow or blood (10% or greater), 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

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### **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**

**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**

**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**

**Drugs**

**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**

Pregnancy in patients with child-bearing potential. Breastfeeding. Undiagnosed abnormal vaginal bleeding.

**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**

Documentation of 1) BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy OR 2) HRD-positive advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy OR 3) recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy OR 4) BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy OR 5) BRCA-mutated HER2-negative Metastatic Breast Cancer OR 6) BRCA-mutated Metastatic Pancreatic Adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen OR 7) HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer which has progressed following prior treatment with enzalutamide or abiraterone.

**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**

**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**

**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**

**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**

## Modafinil

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### Drugs

*modafinil*

### 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.

### Off Label Uses

**MOLINDONE**

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**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**

**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**

**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**



**Drugs****NEULASTA SUBCUTANEOUS SYRINGE****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**

**Drugs**  
**NEXAVAR****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**

**Drugs**  
**NEXLETOL**

**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) Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia), OR B) 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 (maximally tolerated dose may include no statin therapy) OR b) Patient has a documented labeled contraindication to all statins OR c) Patient has experienced rhabdomyolysis, AND 3. Patient has tried and failed ezetimibe. Clinical documentation required for reauthorization includes: 1. Physician attestation of medication's efficacy.

**Age Restriction**

18 years or older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Other Criteria: 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. 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. 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**

**Drugs**  
**NEXLIZET**

**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) Heterozygous familial hypercholesterolemia, OR B) Atherosclerotic cardiovascular disease (ASCVD) established, AND 2. Documentation of any one of the following: a) Patient has been receiving statin therapy at a maximally tolerated dose (maximally tolerated dose may include no statin therapy), OR b) Patient has a documented labeled contraindication to all statins, OR c) Patient has experienced rhabdomyolysis. Clinical documentation required for reauthorization includes: 1. Physician attestation of medication's efficacy.

**Age Restriction**

18 years and older.

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Other Criteria: 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. 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. 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**

**Drugs**  
**NINLARO**

**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**

**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**

**Drugs**  
**NOURIANZ**

**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**

**Drugs**  
**NUBEQA**

**Exclusion Criteria**

**Required Medical Information**

Documentation of 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**



**Drugs**  
**NUCALA**

**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/ $\mu$ L within previous 12 months or greater than or equal to 150 cells/ $\mu$ L 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**

**Drugs**  
**NUEDEXTA**

**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**

**Drugs**  
**NURTEC ODT**

**Exclusion Criteria**

**Required Medical Information**

Documentation that the medication will be used for the acute treatment of migraine with or without aura in adults AND the member has tried and failed two alternatives one of which was a triptan, unless contraindicated.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Reauthorization requires documentation of medication efficacy.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**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**

**Drugs**  
**ODOMZO**

**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**



**Drugs**  
**OPSUMIT**

**Exclusion Criteria**

Pregnancy

**Required Medical Information**

Clinically diagnosed with pulmonary arterial hypertension WHO Group 1 that was confirmed by right heart catheterization. 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**

**Drugs**  
**ORENITRAM**

**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**

**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**

**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

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### 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 as 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/m<sup>2</sup> e. BCM less than 35% male (less than 23% female) and a BMI less than 27 kg/m<sup>2</sup> AND 3. documentation of trial and failure, contraindication, or intolerance to megestrol at doses up to 800mg 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 1g/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**

**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**

**Drugs**  
**PALYNZIQ**

**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**

**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**

**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**

**Drugs**  
**PEMAZYRE**

**Exclusion Criteria**

**Required Medical Information**

Documentation that the member has been diagnosed with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

**Age Restriction**

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**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**

**Drugs**

PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X1-50 MG X1), 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**

**Drugs**  
**PROCYSBI ORAL GRANULES DEL RELEASE IN PACKET**

**Exclusion Criteria**

**Required Medical Information**  
Diagnosis of nephropathic cystinosis

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**  
Through end of benefit year

**Other Criteria**

**Indications**  
All FDA-approved Indications.

**Off Label Uses**



**Drugs**

**PROMACTA ORAL POWDER IN PACKET, PROMACTA ORAL TABLET**

**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**

**Drugs**  
**PULMOZYME**

**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**

## PURIXAN

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### **Drugs** **PURIXAN**

#### **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**

**PYRIMETHAMINE**

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**Drugs**

*pyrimethamine*

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of Toxoplasmosis

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## QUININE

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### **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**

**Drugs**  
**REVLIMID****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**

## RISPERDAL CONSTA

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### 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



**Drugs**  
**ROZLYTREK**

**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**

**Drugs**  
**RYDAPT**

**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**

**Drugs**  
**SAMSCA****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**

## SAPHRIS (asenapine)

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### **Drugs** **SAPHRIS**

#### **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)

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### **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**

**Drugs**  
**SIRTURO****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**

patients 5 years of age and older and weighing at least 15 kg.

**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**

**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**

### Drugs

#### SOMATULINE DEPOT

#### 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

**Drugs**  
**SPRYCEL****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**

**Drugs**  
**STIVARGA****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**



**Drugs**  
**SUCRAID****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**

**Drugs**  
**SUNOSI**

**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**

### **Drugs** **SUTENT**

#### **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**  
**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**

**Drugs**  
**SYNRIBO**

**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**  
**TABRECTA**

**Exclusion Criteria**

**Required Medical Information**  
Diagnosis of Non-small cell lung cancer, metastatic (with mesenchymal-epithelial transition [MET] exon 14 skipping mutation)

**Age Restriction**

**Prescriber Restriction**  
Oncology

**Coverage Duration**  
Through end of benefit year

**Other Criteria**

**Indications**  
All FDA-approved Indications.

**Off Label Uses**

## TAFINLAR

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### 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

**Drugs**  
**TAGRISSO**

**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**



**Drugs**

**TALZENNA ORAL CAPSULE 0.25 MG, 1 MG**

**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  $30 \times 10^9/L$  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**

**Drugs**  
**TAZVERIK**

**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**

**Drugs**  
**TEGSEDI**

**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

*teriparatide*

### Exclusion Criteria

Because of an increased incidence of osteosarcoma, teriparatide 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 teriparatide.

### 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 teriparatide 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** **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**

**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**

**Drugs**

**TOBI PODHALER INHALATION CAPSULE, W/INHALATION DEVICE**

**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**

## Tolvaptan

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### Drugs

*tolvaptan oral tablet 30 mg*

### Exclusion Criteria

#### Required Medical Information

Medication requested is being used to 1)slow kidney function decline AND Liver function laboratory values (ALT, AST and bilirubin) have been reviewed and are appropriate before initiation. OR 2)the treatment of clinically significant hypervolemic and euvolemic hyponatremia

#### Age Restriction

18 years old or older

#### Prescriber Restriction

#### Coverage Duration

Through end of benefit year

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**

**PENNSAID TOPICAL SOLUTION IN METERED-DOSE PUMP**

**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

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### Drugs

*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

**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**

**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**



**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**

**Drugs**  
**TURALIO**

**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**

**Drugs**  
**TYKERB****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**

**Drugs**  
**TYMLOS**

**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**  
**UBRELVY**

**Exclusion Criteria**

**Required Medical Information**

Documentation that the medication will be used for the acute treatment of migraine with or without aura in adults AND the member has tried and failed two alternatives one of which was a triptan, unless contraindicated.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Reauthorization requires documentation of medication efficacy.

**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**

Documentated 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

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### 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

**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**

**Drugs**  
**VENTAVIS****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**

**Drugs**  
**VERSACLOZ****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**

**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**

**Drugs**  
**VIBERZI**

**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 anitdiarrheals (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**

**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**



**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**

**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**

**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

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### 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

**Drugs**  
**VOTRIENT**

**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**

**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**

**Drugs**  
**XALKORI**

**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**

**Drugs**  
**XGEVA**

**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**

**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**

**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), 40 MG/WEEK (20 MG X 2), 40MG TWICE WEEK (80 MG/WEEK), 60 MG/WEEK (20 MG X 3), 60MG TWICE WEEK (120 MG/WEEK), 80 MG/WEEK (20 MG X 4), 80MG TWICE WEEK (160 MG/WEEK)

**Exclusion Criteria**

**Required Medical Information**

Documentation that the medication will be used in 1) 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. OR 2) monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma

**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**

**Drugs**  
**XYREM****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, armodafinil, 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**

**Drugs**  
**YONSA**

**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**

**Drugs**  
**ZEJULA**

**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**

**ZEPOSIA, ZEPOSIA STARTER KIT, ZEPOSIA STARTER PACK**

**Exclusion Criteria**

**Required Medical Information**

Documentation of diagnosis of relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease AND a complete blood cell count and liver function test was completed, reviewed, and deemed appropriate for Zeposia treatment by the prescriber AND patient has had ECG to assess for preexisting cardiac conduction abnormalities prior to starting Zeposia AND inadequate response or intolerance to at least one alternative drug indicated for the treatment of multiple sclerosis.

**Age Restriction**

18 Years of age and older

**Prescriber Restriction**

Neurologist

**Coverage Duration**

Initial 3 months, Continuation of therapy: 12 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**

**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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