2027 PREAUTHORIZATION CRITERIA

MMM Estela, MMM Elite, PMC Max, MMM Plenitud, MMM Supremo, MMM Deluxe, MMM Balance, MMM Valioso, MMM Grandioso, MMM Mega Flex, MMM Diamante Platino, MMM Combo Platino, MMM Dorado Platino, MMM Relax Platino, PMC Premier Platino, MMM Preciso Platino, MMM ELA Relax, MMM ELA Cash, MMM Alianza Relax, MMM Alianza Valor, MMM Alianza Más, MMM Alianza Siempre, MMM Alianza Somos, MMM Alianza Dorado, MMM Alianza Íntegra, MMM Alianza Serena, MMM Alianza Acompaña

PA Criteria (27353)

MSO-PHA-ORG-1380-100526-E

Updated: October 2026

PO BOX 71114 SAN JUAN, P.R. 00936-8015

ACITRETIN

Drugs
Acitretin Oral Cap 10 mg, 17.5 mg, 25 mg

Pending CMS review.

ACTHAR

Drugs
Acthar Gel Injection 80 UNIT/ML Injection
Acthar Gel Subcutaneous Auto-Injector 40 UNIT/0.5ML
Acthar Gel Subcutaneous Auto-Injector 80 UNIT/ML

Exclusion Criteria
1. Scleroderma. 2. Osteoporosis. 3. Systemic fungal infections. 4. Ocular herpes simplex. 5. Recent surgery. 6. History or presence of a peptic ulcer. 7. Congestive heart failure. 8. Uncontrolled Hypertension. 9. Sensitivity to proteins derived from porcine sources. 10. Primary adrenocortical insufficiency or adrenocortical hyperfunction. 11. Infants under 2 years of age who have suspected congenital infections. 12. Concomitant administration of live or live attenuated vaccines in patients receiving immunosuppressive doses of Acthar Gel.

Required Medical Information
1. Diagnosis of any of the following: A) infantile spasms, B) multiple sclerosis, for acute exacerbations, C) rheumatic disorders: as adjunctive therapy for short-term administration in the management of an acute episode or exacerbation of: rheumatoid arthritis, juvenile rheumatoid arthritis (JRA)/juvenile idiopathic arthritis (JIA), or ankylosing spondylitis, D) symptomatic sarcoidosis, E) ophthalmic diseases: keratitis, iritis, iridocyclitis, diffuse posterior uveitis, choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation, F) nephrotic syndrome, for the induction of diuresis or remission of proteinuria, G) dermatologic and allergic states: including severe erythema multiforme, Stevens-Johnson syndrome, or serum sickness, or collagen diseases such as systemic lupus erythematosus (SLE) or systemic dermatomyositis (polymyositis), H) psoriatic arthritis (PsA), as adjunctive treatment of an acute episode or exacerbation. 2. Negative results in Purified Protein Derivative (PPD) test for tuberculosis or patient is currently receiving chemoprophylaxis.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
Initial: 3 months. Renewal: 6 months.

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication..

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required
No

ACTIMMUNE

Drugs
Actimmune Subcutaneous Solution 100 Mcg/0.5ml

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) Chronic Granulomatous Disease (CGD), to reduce frequency and severity of serious infections. B) Severe, malignant osteopetrosis (SMO), to delay time of disease progression. 2. BSA (weight and height). 3. Serum Creatinine (SCr). 4. CBC with differential and PLT. 5. Liver function test (ALT, AST).

Age Restriction
None

Prescriber Restriction
Chronic granulomatous disease: Immunologist, Hematologist, Infectious Diseases Specialist. Severe, Malignant Osteopetrosis: Oncologist, Hematologist, Gynecologist, Rheumatologist, Orthopedist, Endocrinologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required
No

ADAGRASIB

Drugs
Krazati Tablet 200 mg Oral

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required
No

ADAPALENE

Drugs
Adapalene Cream 0.1 % External
Adapalene Gel 0.3 % External

Pending CMS review.

ADCIRCA

Drugs
Alyq Oral Tablet 20 mg
Tadalafil (Pah) Oral Tablet 20 mg

Exclusion Criteria
1. Use for erectile dysfunction. 2. Patients taking nitrates 3. Patients taking Guanylate Cyclase (GC) Stimulators.

Required Medical Information
1. Diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class II / III symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases. 2. Diagnosis confirmed by right heart catheterization. 3. Serum creatinine (Scr) or creatinine clearance. 4.For patient with hepatic impairment: Child Pugh Class. For the FDA-approved indication of pulmonary arterial hypertension, patients currently on Tadalafil may continue therapy if they have a diagnosis of PAH.

Age Restriction
18 years or older

Prescriber Restriction
Pneumologist, Pulmonologist, Cardiologist.

Coverage Duration
Initial: 6 months. Renewal: 12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication..

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required
No

ADEMPAS

Drugs
Adempas Oral Tablet 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg

Pending CMS review.

AFATINIB

Drugs
Gilotrif Oral Tablet 20 mg, 30 mg, 40 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

AFINITOR

Drugs
Everolimus Oral Tablet Soluble 2 mg, 3 mg, 5 mg
Everolimus Oral Tablet 2.5 mg, 5 mg, 7.5 mg, 10 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: A) Postmenopausal women with advanced hormone receptor-positive, HER2 negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole. B) Progressive neuroendocrine tumors of pancreatic origin (PNET) and members with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. C) Advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib. D) Renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery. E) Everolimus Oral Tablet and Everolimus Oral Tablet Soluble are indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. F) Everolimus Oral Tablet Soluble is indicated for the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC associated partial-onset seizures.

Age Restriction
TSC associated with partial onset seizures: For pediatric patient 2 years and older. TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected: for pediatric patients 1 year and older.

Prescriber Restriction
Hematologist, Oncologist, Urologist, Neurologist, Gastroenterologist, Nephrologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required
Yes

AIMOVIG

Drugs
Aimovig Subcutaneous Solution Auto-Injector 140 Mg/Ml, 70 Mg/Ml

Pending CMS review.

AKEEGA

Drugs
Akeega Oral Tablet 100-500 mg, 50-500 mg

Pending CMS review.

ALECENSA

Drugs
Alecensa Oral Capsule 150 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: A) Anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors greater than or equal to 4 cm or node positive), as adjuvant treatment following tumor resection, OR B) ALK-positive metastatic NSCLC. 2. ALK-positive as detected by an FDA-approved test. 3. Liver function test (ALT, AST or bilirubin) and Child Pugh Class.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required
No

ALPRAZOLAM (HRM)

Drugs
Alprazolam Oral Tablet 0.25 MG, 0.5 MG, 1 MG, 2 MG

Pending CMS review.

ALUNBRIG

Drugs
Alunbrig Oral Tablet 180 Mg, 30 Mg, 90 Mg,
Alunbrig Oral Tablet Therapy Pack

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. 2. Liver Function Test (AST, ALT, and total bilirubin) 3. Serum amylase and lipase. 4.Serum creatinine (SCr).

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
Must be covered by Part D benefit.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

Drugs
Dalfampridine ER 10 Mg Oral Tablet

Pending CMS review.

APTIOM

Drugs
Eslicarbazepine Oral Tablet 200 mg, 400 mg, 600 mg, 800 mg

Exclusion Criteria
None

Required Medical Information
1.Diagnosis of Partial-onset seizures. 2. Scr.

Age Restriction
4 years or older

Prescriber Restriction
Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ARCALYST

Drugs
Arcalyst Subcutaneous Solution Reconstituted 220 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: A) Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS). B) Deficiency of Interleukin-1 Receptor Antagonist (DIRA). C) Recurrent Pericarditis (RP) and reduction in risk of recurrence.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
For continuation, patient has experienced disease stability or improvement in clinical symptoms while on therapy.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ARIKAYCE

Drugs
Arikayce Inhalation Suspension 590 MG/8.4ML

Pending CMS review.

AUBAGIO

Drugs
Teriflunomide Oral Tablet 14 mg, 7 mg

Exclusion Criteria
Severe hepatic impairment, pregnancy, and current leflunomide treatment.

Required Medical Information
Diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Age Restriction
18 years or older

Prescriber Restriction
Neurologist or Multiple Sclerosis Specialist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

AUGTYRO

Drugs
Augtyro Oral Capsule 40 Mg, 160 Mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: A) Locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) OR B) Solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity AND have progressed following treatment or have no satisfactory alternative therapy. 2. For non-small cell lung cancer (NSCLC), test results were provided confirming the presence of ROS1 rearrangement, as detected by FDA approved test. 3. For solid tumors, test results were provided confirming the presence of neurotrophic tyrosine receptor kinase (NTRK) gene fusion, as detected by FDA approved test.

Age Restriction
12 years of age and older

Prescriber Restriction
Hematologists, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

AUSTEDO

Drugs
Austedo Oral Tablet 6 mg, 9 mg, 12 mg
Austedo XR Oral Tablet Extended Release 24 Hour 6 mg, 12 mg, 18 mg, 24 mg, 30 mg, 36 mg, 42mg, 48 mg
Austedo XR Patient Titration Oral Tablet Extended-Release Therapy Pack 12 & 18 & 24 & 30 mg

Pending CMS review.

AVMAPKI

Drugs
Avmapki Fakzynja Co-Pack Oral Therapy PACK 0.8 & 200 MG

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of recurrent low-grade serous ovarian cancer (LGSOC) KRAS-mutated. 2. Patient has received prior systemic therapy.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist or Gynecologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

AVONEX

Drugs
Avonex Intramuscular Pen Auto-Injector Kit 30 MCG/0.5ML
Avonex Intramuscular Prefilled Syringe Kit 30 MCG/0.5ML

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of relapsing forms of multiple sclerosis (MS) including isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Age Restriction
18 years or older

Prescriber Restriction
Neurologist or Multiple Sclerosis Specialist

Coverage Duration
12 months

Other Criteria
For new starts: First injection should be administered under the supervision of an appropriately qualified health care professional. For continuation based on both of the following criteria: 1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

AXITINIB

Drugs
Inlyta Oral Tablet 1 mg, 5 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

AYVAKIT

Drugs
Ayvakit Oral Tablet 25 mg, 50 mg, 100 mg, 200 mg, 300 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any the following: A) Gastrointestinal Stromal Tumor (GIST) unresectable or metastatic harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. B) Advanced Systemic Mastocytosis (AdvSM) including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL). C) Indolent Systemic Mastocytosis (ISM). 2. Platelet count must be performed prior to initiating therapy for AdvSM and ISM.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Allergist and Immunologist.

Coverage Duration
12 months

Other Criteria
Limitation of use: Not recommended for the treatment of patients with AdvSM with platelet counts of less than 50 X 10^9/L.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

AZACITIDINE

Drugs
Onureg Oral Tablet 200 mg, 300 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

BAFIERTAM

Drugs
Bafiertam Oral Capsule Delayed Release 95 mg

Exclusion Criteria
Co-administration with dimethyl fumarate or diroximel fumarate.

Required Medical Information
1. Diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. 2. Complete blood cell count (CBC)

Age Restriction
18 years or older

Prescriber Restriction
Neurologist or Multiple Sclerosis Specialist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

BALVERSA

Drugs
Balversa Oral Tablet 3 mg, 4 mg, 5 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of locally advanced or metastatic urothelial carcinoma (mUC) that has: A) susceptible FGFR3 genetic alterations and B) disease has progressed on or after at least one line of prior systemic therapy AND member is not eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Urologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

BANZEL

Drugs
Rufinamide Oral Suspension 40 mg/ml
Rufinamide Oral Tablet 200 mg, 400 mg

Exclusion Criteria
Familial Short QT syndrome.

Required Medical Information
Diagnosis of seizures associated with Lennox-Gastaut Syndrome (LGS).

Age Restriction
None

Prescriber Restriction
Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

BAXDELA

Drugs
Baxdela Intravenous Solution Reconstituted 300 mg
Baxdela Oral Tablet 450 mg

Pending CMS review.

BENLYSTA

Drugs
Benlysta Subcutaneous Solution Auto-injector 200 mg/ml
Benlysta Subcutaneous Solution Prefilled Syringe 200 mg/ml

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: a) Active systemic lupus erythematosus (SLE), OR b) Active lupus nephritis.

Age Restriction
5 years or older

Prescriber Restriction
Rheumatologist or Nephrologist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

BESREMI

Drugs
Besremi Subcutaneous Solution Prefilled Syringe 500 MCG/ML

Exclusion Criteria
1) Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation or suicide attempt. 2) Hypersensitivity to interferon. 3) Hepatic impairment (Child-Pugh B or C). 4) History or presence of active serious or untreated autoimmune disease. 5) Immunosuppressed transplant recipients.

Required Medical Information
Diagnosis of polycythemia vera.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Immunologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

BINIMETINIB

Drugs
Mektovi Oral Tablet 15 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: a) unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test, in combination with Braftovi (encorafenib), or b) metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test, in combination with Braftovi (encorafenib).

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

BOSUTINIB

Drugs
Bosulif Oral Tablet 100 mg, 400 mg, 500mg
Bosulif Oral Capsule 50 mg, 100 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

BRIVIACT

Drugs
Brivaracetam Oral Solution 10 mg/ml
Brivaracetam Oral Tablet 10 mg, 25 mg, 50 mg, 75 mg, 100 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis: partial-onset seizures.

Age Restriction
None

Prescriber Restriction
Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

BRUKINSA

Drugs
Brukinsa Oral Tablet 160 Mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: A) Mantle cell lymphoma (MCL) who have received at least one prior therapy. B) Waldenstroms macroglobulinemia (WM). C) Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen. D) Chronic lymphocytic leukemia (CLL) or Small lymphocytic lymphoma (SLL). E) Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

BUPHENYL

Drugs
Sodium Phenylbutyearate Oral Powder 3 gm/tsp
Sodium Phenylbutyearate Oral Tablet 500 mg

Exclusion Criteria
Acute hyperammonemia (do not use for emergency management)

Required Medical Information
1. Diagnosis of any of the following: A) Adjunctive therapy in chronic management of patients with urea cycle disorders involving deficiencies of carbamyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). It is indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). B) Late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy. 2. BSA.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

B VS D DRUGS

Drugs

Acetylcysteine Solution 10 % Inhalation
Acetylcysteine Solution 20 % Inhalation
Acyclovir Sodium Solution 50 mg/ml Intravenous
Albuterol Sulfate Nebulization Solution 2.5 mg/0.5ml Inhalation
Albuterol Sulfate Nebulization Solution (2.5 MG/3ML) 0.083% Inhalation
Albuterol Sulfate Nebulization Solution 0.63 mg/3ml Inhalation
Albuterol Sulfate Nebulization Solution 1.25 mg/3ml Inhalation
Amphotericin B Liposome Suspension Reconstituted 50 mg Intravenous
Amphotericin B Solution Reconstituted 50 mg Intravenous
Ampicillin Sodium Solution Reconstituted 1 gm Injection
Ampicillin Sodium Solution Reconstituted 10 gm Intravenous
Aprepitant Oral Capsule 125 mg
Aprepitant Oral Capsule 40 mg
Aprepitant Capsule Therapy Pack 80 & 125 MG Oral
Aprepitant Oral Capsule 80 mg
Azathioprine Oral Tablet 50 mg, 75 mg, 100 mg
Bivigam Intravenous Solution 5 gm/50ml, 10 gm/100ml
Budesonide Suspension 0.25 mg/2ml Inhalation
Budesonide Suspension 0.5 mg/2ml Inhalation
Budesonide Suspension 1 mg/2ml Inhalation
Caspofungin Acetate Solution Reconstituted 50 mg Intravenous
Caspofungin Acetate Solution Reconstituted 70 mg Intravenous
Cefoxitin Sodium Solution Reconstituted 1 gm Intravenous
Cefoxitin Sodium Solution Reconstituted 10 gm Injection
Cefoxitin Sodium Solution Reconstituted 2 gm Intravenous
Cefuroxime Sodium Solution Reconstituted 1.5 gm Intravenous
Cefuroxime Sodium Solution Reconstituted 750 mg Injection
Clinimix/Dextrose (4.25/10) Solution 4.25 % Intravenous
Clinimix/Dextrose (4.25/5) Solution 4.25 % Intravenous
Clinimix/Dextrose (5/15) Solution 5 % Intravenous
Clinimix/Dextrose (5/20) Solution 5 % Intravenous
Colistimethate Sodium (Cba) Solution Reconstituted 150 mg Injection
Cromolyn Sodium Nebulization Solution 20 mg/2ml Inhalation
Cyanocobalamin Solution 1000 MCG/ML Injection (applies only to MMM Platino Plan members)
Cyclophosphamide Oral Capsule 25 mg
Cyclophosphamide Oral Capsule 50 mg
Cyclophosphamide Tablet 50 MG Oral
Cyclosporine Oral Capsule 100 mg
Cyclosporine Oral Capsule 25 mg
Cyclosporine Modified Oral Capsule 100 mg
Cyclosporine Modified Oral Capsule 25 mg
Cyclosporine Modified Oral Capsule 50 mg
Cyclosporine Modified Oral Solution 100 mg/ml
Dronabinol Oral Capsule 10 mg
Dronabinol Oral Capsule 2.5 mg

Dronabinol Oral Capsule 5 mg
Emend Oral Suspension Reconstituted 125 mg
Engerix-B Suspension Prefilled Syringe 10 MCG/0.5ML Injection
Engerix-B Suspension Prefilled Syringe 20 MCG/ML Injection
Engerix-B Suspension 20 Mcg/ml Injection
Envarsus XR Tablet Extended Release 24 Hour 0.75 MG Oral
Envarsus XR Tablet Extended Release 24 Hour 1 MG Oral
Envarsus XR Tablet Extended Release 24 Hour 4 MG Oral
Everolimus Oral Tablet 0.25 mg
Everolimus Oral Tablet 0.5 mg
Everolimus Oral Tablet 0.75 mg
Everolimus Oral Tablet 1 mg
Fluconazole In Sodium Chloride Solution 200-0.9 mg/100ml-% Intravenous
Fluconazole In Sodium Chloride Solution 400-0.9 mg/200ml-% Intravenous
Formoterol Fumarate Nebulization Solution 20 Mcg/ml Inhalation
Gamunex-C Solution 1 gm/10ml Injection
Gengraf Oral Capsule 100 mg
Gengraf Oral Capsule 25 mg
Granisetron Hcl Oral Tablet 1 mg
Heplisav-B Solution Prefilled Syringe 20 Mcg/0.5ml Intramuscular
Infed Solution 50 MG/ML Injection (applies only to MMM Platino Plan members)
Intralipid Emulsion 20 % Intravenous
Intralipid Emulsion 30 % Intravenous
Ipratropium Bromide Solution 0.02 % Inhalation
Ipratropium-Albuterol Solution 0.5-2.5 (3) mg/3ml Inhalation
Jylamvo Oral Solution 2 MG/ML
Jynneos Suspension 0.5 ml Subcutaneous
Levalbuterol Hcl Nebulization Solution 0.31 mg/3ml Inhalation
Levalbuterol Hcl Nebulization Solution 0.63 mg/3ml Inhalation
Levalbuterol Hcl Nebulization Solution 1.25 mg/0.5ml Inhalation
Levalbuterol Hcl Nebulization Solution 1.25 mg/3ml Inhalation
Methotrexate Sodium (Pf) Solution Injection 50 MG/2ML,
Methotrexate Sodium Solution 50 mg/2ml Injection
Methotrexate Sodium Oral Tablet 2.5 MG
Moxifloxacin HCl in NaCl Solution 400 mg/250ml Intravenous
Mycophenolate Mofetil Oral Capsule 250 mg
Mycophenolate Mofetil Oral Suspension Reconstituted 200 mg/ml
Mycophenolate Mofetil Oral Tablet 500 mg
Mycophenolate Sodium Oral Tablet Delayed Release 180 mg
Mycophenolate Sodium Oral Tablet Delayed Release 360 mg
Nafcillin Sodium Solution Reconstituted 1 gm Injection
Nafcillin Sodium Solution Reconstituted 10 gm Intravenous
Nafcillin Sodium Solution Reconstituted 2 gm Injection
Neoral Oral Capsule 100 mg
Neoral Oral Capsule 25 mg
Neoral Oral Solution 100 mg/ml
Nutrilipid Emulsion 20 % Intravenous
Octagam Solution 1 GM/20ML Intravenous
Octagam Solution 2 GM/20ML Intravenous
Octreotide Acetate Solution 100 Mcg/ml Injection

Octreotide Acetate Solution 1000 Mcg/ml Injection
Octreotide Acetate Solution 200 Mcg/ml Injection
Octreotide Acetate Solution 500 Mcg/ml Injection
Ondansetron Hcl Oral Solution 4 mg/5ml
Ondansetron Hcl Oral Tablet 4 mg
Ondansetron Hcl Oral Tablet 8 mg
Ondansetron Oral Tablet Dispersible 4 mg
Ondansetron Oral Tablet Dispersible 8 mg
Pentamidine Isethionate Inhalation Solution Reconstituted 300 mg
Pentamidine Isethionate Injection Solution Reconstituted 300 mg
Polymyxin B Sulfate Solution Reconstituted 500000 Unit Injection
Premasol Solution 10 % Intravenous
Prograf Oral Packet 0.2 mg
Prograf Oral Packet 1 mg
Prosol Solution 20 % Intravenous
Pulmozyme Solution 2.5 mg/2.5ml Inhalation
Recombivax HB Suspension 10 Mcg/ml Injection
Recombivax HB Suspension 40 Mcg/ml Injection
Recombivax HB Suspension 5 Mcg/0.5ml Injection
Recombivax HB Suspension Prefilled Syringe 10 Mcg/ml Injection
Recombivax HB Suspension Prefilled Syringe 5 Mcg/0.5ml Injection
Sirolimus Oral Solution 1 mg/ml
Sirolimus Oral Tablet 0.5 mg
Sirolimus Oral Tablet 1 mg
Sirolimus Oral Tablet 2 mg
Tacrolimus Oral Capsule 0.5 mg
Tacrolimus Oral Capsule 1 mg
Tacrolimus Oral Capsule 5 mg
Tacrolimus ER Oral Capsule Extended Release 24 Hour 0.5 mg, 1 mg, 5 mg
Tenivac Injectable 5-2 LFU Intramuscular
Tenivac Injectable 5-2 LFU Intramuscular (Injection)
Tobramycin Nebulization Solution 300 mg/5ml Inhalation
Tobramycin Sulfate Solution 10 mg/ml Injection
Tobramycin Sulfate Solution 80 mg/2ml Injection
TPN Electrolytes Solution Intravenous
Travasol Solution 10 % Intravenous
Trophamine Solution 10 % Intravenous
Xatmep Solution 2.5 MG/ML Oral

Exclusion Criteria
None

Required Medical Information
None

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
None

Other Criteria
None

Indications
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.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required
No

CABOMETYX

Drugs
Cabometyx Oral Tablet 20 mg, 40 mg, 60 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: 1) Advanced renal cell carcinoma (RCC). 2) Advanced renal cell carcinoma, as a first-line treatment in combination with nivolumab. 3) Hepatocellular carcinoma (HCC) previously treated with sorafenib. 4) Locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible. 5. Previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET) OR 6. Previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors (epNET).

Age Restriction
For DTC, pNet or epNET: 12 years or older. Other: 18 years or older.

Prescriber Restriction
Oncologist, Hematologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

CABOZANTINIB

Drugs
Cometriq (100 MG Daily Dose) Kit 80 & 20 mg Oral
Cometriq (140 MG Daily Dose) Kit 3 x 20 mg & 80 mg Oral
Cometriq (60 MG Daily Dose) Kit 20 mg Oral

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

CALQUENCE

Drugs
Calquence Oral Tablet 100 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: A) mantle cell lymphoma (MCL) who have received at least one prior therapy, B) mantle cell lymphoma (MCL), previously untreated, member is ineligible for autologous hematopoietic stem cell transplantation (HSCT) AND will be used In combination with bendamustine and rituximab, OR C) Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

CAMZYOS

Drugs
Camzyos Oral Capsule 2.5 mg, 5 mg, 10 mg, 15 mg

Exclusion Criteria
1. Strong CYP2C19 inhibitors. 2. Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers.

Required Medical Information
1. Diagnosis of symptomatic New York Heart Association (NYHA) class II to III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms. 2. Baseline left ventricular ejection fraction (LVEF %).

Age Restriction
18 years or older

Prescriber Restriction
Cardiologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

CARBAGLU

Drugs
Carglumic Acid Oral Tablet 200 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: A) Acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS), as adjunctive therapy. B) Chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase, as maintenance therapy. C) Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA), as adjunctive therapy.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All Medically-accepted Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

CAYSTON

Drugs
Cayston Inhalation Solution Reconstituted 75 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of Pseudomonas aeruginosa in patients with cystic fibrosis.

Age Restriction
7 years or older

Prescriber Restriction
Pulmonologist, Infectious Disease Specialist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

CHOLBAM

Drugs
Cholbam Oral Capsule 50 mg, 250 mg

Pending CMS review.

CLONAZEPAM (HRM)

Drugs
Clonazepam Oral Tablet 0.5 MG, 1MG, 2 MG
Clonazepam Oral Tablet Dispersible 0.125 MG, 0.25 MG, 0.5 MG, 1 MG, 2 MG

Pending CMS review.

CLORAZEPATE (HRM)

Drugs
Clorazepate Dipotassium Oral Tablet 3.75 MG, 7.5 MG, 15 MG

Pending CMS review.

COPIKTRA

Drugs
Copiktra Oral Capsule 15 mg, 25 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of one of the following: A) Relapsed or refractory chronic lymphocytic leukemia (CLL), OR B) Small lymphocytic lymphoma (SLL) after at least two prior therapies.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

CORLANOR

Drugs
Ivabradine HCl Oral Tablet 5 mg, 7.5 mg

Exclusion Criteria
1. Acute decompensated heart failure. 2. Clinically significant hypotension 3. Sick sinus syndrome, sinoatrial block or 3rd degree AV block, unless a functioning demand pacemaker is present. 4. Clinically significant bradycardia. 5. Concomitant use of strong cytochrome CYP3A4 inhibitors. 6. Severe hepatic impairment (Child-Pugh C). 7. Heart rate maintained exclusively by the pacemaker.

Required Medical Information
1. Diagnosis of stable, symptomatic chronic heart failure with left ventricular ejection fraction less or equal 35%, who are in sinus rhythm with resting heart rate greater or equal 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use. Patient is currently on maximally tolerated doses of ACEI or ARB unless intolerant or contraindicated, OR 2) Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients.

Age Restriction
For stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction: 18 years or older. For stable symptomatic heart failure due to dilated cardiomyopathy: 6 months or older.

Prescriber Restriction
Cardiologist

Coverage Duration
12 months

Other Criteria
For continuation, member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

CORTROPHIN

Drugs
Cortrophin Gel 80 UNIT/ML Injection
Cortrophin Gel Prefilled Syringe 40 UNIT/0.5ML Subcutaneous
Cortrophin Gel Prefilled Syringe 80 UNIT/ML Subcutaneous

Exclusion Criteria
Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins derived from porcine sources and primary adrenocortical insufficiency or adrenocortical hyperfunction.

Required Medical Information
1. Diagnosis of any of the following: A) Rheumatic disorders: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis or acute gouty arthritis. B) Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus or systemic dermatomyositis (polymyositis). C) Dermatologic diseases: Severe erythema multiforme (Stevens-Johnson syndrome) or severe psoriasis. D) Allergic states: atopic dermatitis or serum sickness. E) Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis or anterior segment inflammation. F) Respiratory diseases: symptomatic sarcoidosis. G) Edematous states: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. H) Nervous system: acute exacerbations of multiple sclerosis. 2. Negative results in Purified Protein Derivative (PPD) test for tuberculosis or patient is currently receiving chemoprophylaxis.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
Initial: 3 months. Renewal: 6 months.

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications

All FDA-approved Indications.**Off Label Uses**
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

COSENTYX

Drugs
Cosentyx (300 MG Dose) Solution Prefilled Syringe 150 MG/ML Subcutaneous
Cosentyx Sensoready (300 MG) Solution Auto-Injector 150 MG/ML Subcutaneous
Cosentyx Solution Prefilled Syringe 75 MG/0.5ML Subcutaneous
Cosentyx UnoReady Solution Auto-Injector 300 MG/2ML Subcutaneous

Pending CMS review.

COTELLIC

Drugs
Cotellic Oral Tablet 20 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: A) Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib, OR B) Histiocytic neoplasms. 2. For melanoma, genetic test confirming the presence of BRAF V600E or V600K mutation in tumor specimens.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

CRESEMBA

Drugs
Cresemba Oral Capsule 74.5 MG, 186 MG

Exclusion Criteria
1. Coadministration with strong CYP3A4 inhibitors, such as ketoconazole or high-dose ritonavir. 2. Coadministration with strong CYP3A4 inducers, such as rifampin, carbamazepine, St. John's wort, or long-acting barbiturates. 3. Use in patients with familial short QT syndrome.

Required Medical Information
1. Diagnosis of Invasive aspergillosis or Invasive mucormycosis.

Age Restriction
6 years of age and older who weigh 16 kilograms (kg) and greater.

Prescriber Restriction
Infectious Disease Specialist or Pulmonologist.

Coverage Duration
6 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

CYCLOBENZAPRINE (HRM)

Drugs
Cyclobenzaprine HCl Oral Tablet 5 MG, 7.5 MG, 10 MG

Exclusion Criteria
None

Required Medical Information
1.Diagnosis 2. Physician attestation that he/she has assessed risk versus benefit in using this High Risk Medication (HRM) and would still like to initiate/continue therapy.

Age Restriction
Prior authorization (PA) is mandated for members aged 65 and older.

Prescriber Restriction
None

Coverage Duration
21 days

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

DABRAFENIB

Drugs
Tafinlar Oral Capsule 50 mg, 75 mg
Tafinlar Oral Tablet Soluble 10 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

DANZITEN

Drugs
Danziten Oral Tablet 71 Mg, 95 Mg

Exclusion Criteria
Hypokalemia, hypomagnesemia, or long QT syndrome.

Required Medical Information
Diagnosis of one of the following: a) Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase, or b) Chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib.

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
For CML, new patient must have Ph-positive CML for approval of Danziten (nilotinib).

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

DAURISMO

Drugs
Daurismo Oral Tablet 100 Mg, 25 Mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of newly-diagnosed acute myeloid leukemia (AML), to be used in combination with low-dose cytarabine, for the treatment of patients who are equal or more 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required
Yes

DAYBUE

Drugs
Daybue Oral Solution 200 Mg/Ml

Pending CMS review.

DIACOMIT

Drugs
Diacomit Oral Capsule 250 mg, 500 mg
Diacomit Oral Packet 250 mg, 500 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of seizures associated with Dravet syndrome in patients taking clobazam.

Age Restriction
6 months or older

Prescriber Restriction
Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

DIAZEPAM (HRM)

Drugs
Diazepam Intensol Oral Concentrate 5 MG/ML
Diazepam Oral Solution 5 MG/5ML
Diazepam Oral Tablet 2 MG 5 MG, 10 MG

Pending CMS review.

DISEASE-MODIFYING ANTIRHEUMATIC DRUGS

Drugs
Hadlima PushTouch Solution Auto-Injector 40 MG/0.4ML Subcutaneous
Hadlima PushTouch Solution Auto-Injector 40 MG/0.8ML Subcutaneous
Hadlima Solution Prefilled Syringe 40 MG/0.4ML Subcutaneous
Hadlima Solution Prefilled Syringe 40 MG/0.8ML Subcutaneous
Simlandi (1 Pen) Auto-Injector Kit 80 MG/0.8ML Subcutaneous
Simlandi (2 Pen) Auto-Injector Kit 40 MG/0.4ML Subcutaneous
Simlandi (2 Syringe) Prefilled Syringe Kit 20 MG/0.2ML Subcutaneous
Simlandi (2 Syringe) Prefilled Syringe Kit 40 MG/0.4ML Subcutaneous

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) Moderately to severely active Rheumatoid Arthritis (RA), to reduce signs and symptoms, inducing major clinical response, inhibiting the progression of structutral damage, and improving physical function. B) Moderately to severely active polyarticular Juvenile Idiopathic Arthritis (JIA) to reduce signs and symptoms. C)Active Psoriatic Arthritis (PsA), to reduce signs and symptoms, inhibiting the progression of structural damage, and improving physical function. D) Ankylosing Spondylitis (AS) to reduce signs and symptoms. E) Moderately to severely active Crohns Disease (CD). F) Moderately to severely active Ulcerative Colitis (UC). G) Moderate to severe chronic Plaque Psoriasis (Ps) in patients who are candidates for systemic therapy or phototherapy. H) Moderate to severe Hidradenitis Suppurativa (HS). I) Uveitis (UV), for the treatment of non-infectious intermediate, posterior, and panuveitis. 2. Negative test results PPD for latent tuberculosis.

Age Restriction
None

Prescriber Restriction
For Rheumatoid Arthritis (RA) and Ankylosing Spondylitis (AS): Rheumatologist. For Psoriasis with Arthropathy(PsA): Rheumatologist or Dermatologist. For Crohns Disease (CD): Gastroenterologist. For Plaque Psoriasis (Ps): Dermatologist or Rheumatologist. For Juvenile Idiopathic Arthritis (JIA): Rheumatologist. For Ulcerative Colitis (UC): Gastroenterologist. For Hidradenitis Suppurativa (HS): Dermatologist. For Uveitis (UV): Ophtalmologist.

Coverage Duration
12 months

Other Criteria
1. For adults with Rheumatoid Arthritis: one (1) DMARD (brand or generic, oral or injectable) for at least 3 months. DMARD (E.g., anakinra, auranofin (Ridaura), azathioprine, cyclosporine, d-penicillamine (Cuprimine), etanercept, gold sodium thiomalate (Aurolate, generic), hydroxychloroquine, infliximab, leflunomide, MTX, or sulfasalazine). 2. For continuation based on both of the following criteria: (a) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (b) The member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required
Yes

DRIZALMA

Drugs
Drizalma Sprinkle Oral Capsule Delayed Release Sprinkle 20 mg, 30mg, 40mg, 60mg
Duloxetine Hcl Oral Capsule Delayed Release Particles 80 mg, 90 mg, 120 mg

Exclusion Criteria
Serotonin Syndrome and MAOIs: Do not use MAOIs intended to treat psychiatric disorders with (duloxetine) DRIZALMA SPRINKLE or within 5 days of stopping treatment with (duloxetine) DRIZALMA SPRINKLE. Do not use (duloxetine) DRIZALMA SPRINKLE within 14 days of stopping an MAOI intended to treat.

Required Medical Information
1. Diagnosis of one of the following: a) Major Depressive Disorder (MDD), b) Generalized Anxiety Disorder (GAD), c) Diabetic Peripheral Neuropathic Pain (DPNP), d) Fibromyalgia (FM) or e) Chronic Musculoskeletal Pain (CMP). 2. Member has a documented intolerance, contraindication, or treatment failure with generic duloxetine capsules OR 3. Member is unable to swallow the oral dosage form of duloxetine due to a clinical condition such as but not limited to the following: a) Dysphagia, OR b) Oral/motor difficulties.

Age Restriction
GAD: 7 years of age and older. FM, MDD, DPNP, CMP: 18 years of age and older.

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

DULAGLUTIDE (GLP-1)

Drugs
Trulicity Subcutaneous Solution Auto-Injector 0.75 mg/0.5ml, 1.5 mg/0.5ml, 3 mg/0.5ml, 4.5 mg/0.5ml

Exclusion Criteria
Personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine. Neoplasia syndrome type 2 (MEN 2).

Required Medical Information
1. Diagnosis of one of the following: A) Type 2 diabetes mellitus for glycemic control or B) Type 2 diabetes mellitus with established cardiovascular disease, to reduce the risk of major adverse cardiovascular event. 2. A1C.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

DUPIXENT

Drugs
Dupixent Solution Subcutaneous Auto-Injector 200 mg/1.14ml, 300 mg/2ml
Dupixent Solution Subcutaneous Prefilled Syringe 200 mg/1.14ml, 300 mg/2ml

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: (A) Moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. (B) Moderate to severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma, as add-on maintenance therapy. (C) Inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP). (D) Eosinophilic esophagitis (EoE). (E) Prurigo Nodularis (PN), (F) Chronic Obstructive Pulmonary Disease (COPD), as an add-on maintenance treatment of adult patients with inadequately controlled chronic COPD and an eosinophilic phenotype. (G) Chronic Spontaneous Urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment. (H) Bullous Pemphigoid, or (I) Allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery.

Age Restriction
For atopic dermatitis: 6 months or older. For asthma or AFRS: 6 years or older. For CRSwNP: 12 years or older. For Prurigo Nodularis, COPD or BP: 18 years or older. For eosinophilic esophagitis: 1 year and older. For CSU: 2 year and older.

Prescriber Restriction
Prescribed by or in consultation with a Dermatologist, Allergist, Pneumologist, Pulmonologist, Immunologist, Otorhinolaryngologist, or Gastroenterologist.

Coverage Duration
Initial: 6 months. Renewal: 12 months.

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

EMGALITY

Drugs
Emgality (300 MG Dose) Subcutaneous Solution Prefilled Syringe 100 mg/ml
Emgality Subcutaneous Solution Auto-Injector 120 mg/ml
Emgality Subcutaneous Solution Prefilled Syringe 120 mg/ml

Pending CMS review.

ENBREL

Drugs
Enbrel Subcutaneous Solution Prefilled Syringe 25 mg/0.5ml
Enbrel Subcutaneous Solution Prefilled Syringe 50 mg/ml
Enbrel SureClick Subcutaneous Solution Auto-injector 50 mg/ml
Enbrel Mini Subcutaneous Solution Cartridge 50 mg/ml
Enbrel Subcutaneous Solution 25 mg/0.5ml

Pending CMS review.

ENCORAFENIB

Drugs
Braftovi Oral Capsule 75 mg

Pending CMS review.

Drugs
L-Glutamine Packet 5 GM Oral

Pending CMS review.

ENSACOVE

Drugs
Ensacove Oral Capsule 25 MG, 100 MG

Exclusion Criteria
None

Required Medical Information
Diagnosis of anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC).

Age Restriction
18 years of age or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ENTYVIO

Drugs
Entyvio Pen Solution Subcutaneous Auto-Injector 108 MG/0.68ML

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: moderately to severely active ulcerative colitis (UC) or moderately to severely active Crohn's disease (CD). 2. Member has completed induction therapy with intravenous vedolizumab.

Age Restriction
18 years of age or older

Prescriber Restriction
Gastroenterologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

EPCLUSA

Drugs
Sofosbuvir-Velpatasvir Oral Tablet 400-100 mg

Pending CMS review.

EPIDIOLEX

Drugs
Epidiolex Oral Solution 100 mg/ml

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex. 2. Serum transaminases (ALT and AST) and total bilirubin levels. 3. Weight.

Age Restriction
1 year or older

Prescriber Restriction
Neurologist, Geneticist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ERIVEDGE

Drugs
Erivedge Oral Capsule 150 MG

Exclusion Criteria
None

Required Medical Information
Diagnostic of treatment of adults with metastatic basal cell carcinoma, OR with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery and who are not candidates for radiation.

Age Restriction
18 years or older

Prescriber Restriction
Dermatologist, Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ERLEADA

Drugs
Erleada Oral Tablet 60 mg, 240 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following type of prostate cancer: A) Non metastatic castration-resistant. B) Metastatic castration-sensitive.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Urologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ERYTHROID STIMULANTS

Drugs
Retacrit Injection Solution 2,000 UNIT/ML
Retacrit Injection Solution 3,000 UNIT/ML
Retacrit Injection Solution 4,000 UNIT/ML
Retacrit Injection Solution 10,000 UNIT/ML
Retacrit Injection Solution 20,000 UNIT/ML
Retacrit Injection Solution 40,000 UNIT/ML

Pending CMS review.

ESBRIET

Drugs
Pirfenidone Oral Capsule 267 mg
Pirfenidone Oral Tablet 267 mg, 534 mg, 801 mg

Pending CMS review.

ESTAZOLAM (HRM)

Drugs
Estazolam Oral Tablet 1 MG, 2MG

Pending CMS review.

EUCRISA

Drugs
Eucrisa External Ointment 2 %

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of mild to moderate atopic dermatitis. 2. History of failure, contraindication, or intolerance to one of the following topical therapies: a) topical corticosteroid (e.g., fluocinolone acetonide, mometasone furoate, desonide). b) topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus).

Age Restriction
3 months of age and older.

Prescriber Restriction
Prescribed by, or in consultation with, an Allergist, Dermatologist or Immunologist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

EULEXIN

Drugs
Eulexin Oral Capsule 125 mg

Exclusion Criteria
Severe hepatic impairment

Required Medical Information
1. Diagnosis of prostate cancer. 2. AST, ALT.

Age Restriction
18 years or older

Prescriber Restriction
Urologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

EVRYSDI

Drugs
Evrysdi Oral Solution Reconstituted 0.75 mg/ml
Evrysdi Oral Tablet 5 mg

Pending CMS review.

EXJADE

Drugs
Deferasirox Oral Tablet Soluble 125 mg, 250 mg, 500 mg

Exclusion Criteria
1. Advanced malignancies. 2. Platelet counts less than 50 x 10^(9)/L. 3. Poor performance status. 4. High risk myelodysplastic syndromes. 5. Estimated GFR less than 40 mL/min/1.73 m2.

Required Medical Information
Diagnosis of chronic iron overload due to blood transfusions OR iron overload in non-transfusion-dependent thalassemia (NTDT) syndromes. For transfusional iron overload: GFR, serum creatinine in duplicate, serum transaminases (AST and ALT), bilirubin, serum ferritin, units of PRBC transfused, serum electrolytes, urinalysis. For Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes: LIC of at least 5 mg Fe/g, serum ferritin greater than 300 mcg/L, GFR, serum creatinine in duplicate, serum transaminases (AST and ALT), bilirubin, serum electrolytes, urinalysis.

Age Restriction
Iron Overload Due to Blood Transfusions: 2 years of age or older. NTDT: 10 years of age or older

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

FASENRA

Drugs
Fasenra Pen Solution Auto-Injector 30 MG/ML Subcutaneous
Fasenra Solution Prefilled Syringe 30 MG/ML Subcutaneous

Exclusion Criteria
None

Required Medical Information
Diagnosis of one of the following: A) severe asthma with an eosinophilic phenotype, as add-on maintenance treatment. B) eosinophilic granulomatosis with polyangiitis (EGPA), or C) Hypereosinophilic syndrome (HES) without an identifiable non hematologic secondary cause.

Age Restriction
Asthma: 6 years or older. EGPA: 18 years or older. HES: 12 years or older.

Prescriber Restriction
Prescribed by or in consultation with a Allergist, Pneumologist, Pulmonologist, Immunologist, Hematologist or Rheumatologist.

Coverage Duration
Initial: 6 months. Renewal: 12 months.

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

FERRIPROX

Drugs
Ferriprox Oral Solution 100 mg/ml
Deferiprone Oral Tablet 500 mg, 1000mg

Pending CMS review.

FILGRASTIM

Drugs
Zarxio Injection Solution Prefilled Syringe 300 MCG/0.5ML
Zarxio Injection Solution Prefilled Syringe 480 MCG/0.8ML
Nivestym Injection Solution 300 MCG/ML
Nivestym Injection Solution 480 MCG/1.6ML
Nivestym Injection Solution Prefilled Syringe 300 MCG/0.5ML
Nivestym Injection Solution Prefilled Syringe 480 MCG/0.8ML

Exclusion Criteria
None

Required Medical Information
1. CBC and platelet count. 2. Weight.

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist or Infectious Disease Specialist

Coverage Duration
6 months

Other Criteria
Subject to BvsD review. For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

FILSPARI

Drugs
Filspari Oral Tablet 200 mg, 400 mg

Exclusion Criteria
Concomitant use of renin-angiotensin3-aldosterone system (RAAS) inhibitors, endothelin receptor antagonist (ERAs) or aliskiren.

Required Medical Information
1.Diagnosis of primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression, to slow kidney function decline. 2. Diagnosis of focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome to reduce proteinuria 3. Liver enzymes (AST, ALT).

Age Restriction
For (IgAN): 18 years or older. For (FSGS): 8 year or older.

Prescriber Restriction
Nephrologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

FINTEPLA

Drugs
Fintepla Oral Solution 2.2 mg/ml

Exclusion Criteria
Use within 14 days of the administration of monoamine oxidase inhibitors.

Required Medical Information
1. Diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome. 2. Echocardiogram. 3. Weight 4. CrCl 5. Liver function test.

Age Restriction
2 years or older

Prescriber Restriction
Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

FIRAZYR

Drugs
Icatibant Acetate Subcutaneous Solution Prefilled Syringe 30 MG/3ML
Sajazir Subcutaneous Solution Prefilled Syringe 30 MG/3ML

Exclusion Criteria
None

Required Medical Information
Diagnosis of acute attacks of hereditary angioedema (HAE).

Age Restriction
18 years or older

Prescriber Restriction
Prescribed by, or in consultation with, an allergist/immunologist or a physican that specializes in the treatment of HAE or related disorders.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: 1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

FIRMAGON

Drugs
Firmagon (240 MG Dose) Subcutaneous Solution Reconstituted 120 mg/VIAL
Firmagon Subcutaneous Solution Reconstituted 80 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of advanced prostate cancer.

Age Restriction
None

Prescriber Restriction
Oncologist, Urologist

Coverage Duration
12 months

Other Criteria
Subject to B vs D review.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

FOTIVDA

Drugs
Fotivda Oral Capsule 0.89 mg, 1.34 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC), following two or more prior systemic therapies.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

FRUZAQLA

Drugs
Fruzaqla Oral Capsule 1 Mg, 5mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy. 2. AST, ALT, bilirubin

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

FYCOMPA

Drugs
Perampanel Oral Suspension 0.5 mg/ml
Perampanel Oral Tablet 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg

Pending CMS review.

GATTEX

Drugs
Gattex Subcutaneous KIT 5 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of short bowel syndrome (SBS) AND patient is dependent on parenteral support. Baseline bilirubin, alkaline phosphatase, lipase, and amylase levels within 6 months prior to starting treatment. Adults: Colonoscopy of the entire colon with removal of polyps within 6 months prior to initiation. Pediatric patients: Fecal occult blood testing followed by colonoscopy/sigmoidoscopy for unexplained blood in the stool within 6 months prior to initiation. 2. Weight 3. GFR

Age Restriction
1 year or older

Prescriber Restriction
Gastroenterologist

Coverage Duration
Initial: 6 months. Renewal: 12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

GAVRETO

Drugs
Gavreto Oral Capsule 100 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) Metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer as detected by an FDA approved test (NSCLC). B) Advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). 2. ALT and AST prior to initiating therapy.

Age Restriction
For advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate): 12 years or older.

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

GILENYA

Drugs
Fingolimod Oral Capsule 0.5 mg

Exclusion Criteria
1. Recent (within the last 6 months) myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure. 2. History of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. 3. Baseline QTc interval equal or more than 500 milliseconds. 4. Treatment with Class Ia or Class III anti-arrhythmic drugs.

Required Medical Information
Diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting diseasse, and active secondary progressive disease.

Age Restriction
10 years or older

Prescriber Restriction
Neurologist, Mutiple Sclerosis Specialist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

GLATIRAMER

Drugs
Glatiramer Acetate Subcutaneous Solution Prefilled Syringe 40 Mg/Ml

Exclusion Criteria
None

Required Medical Information
Diagnosis of relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Age Restriction
18 years or older

Prescriber Restriction
Neurologist, Mutiple Sclerosis Specialist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and ((2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

GLEOSTINE

Drugs
Lomustine Oral Capsule 10 Mg, 100 Mg, 40 Mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) Brain tumors, primary and metastatic, following appropriate surgical and/or radiotherapeutic procedures. B) Hodgkin’s lymphoma in combination with other chemotherapies, following disease progression with initial chemotherapy. 2. Body surface area (BSA).

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist, Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

GOMEKLI

Drugs
Gomekli Oral Capsule 1 mg, 2mg
Gomekli Oral Tablet Soluble 1 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection.

Age Restriction
2 years of age and older.

Prescriber Restriction
Oncologist, Neurologist or Geneticists.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

Drugs
Norditropin Flexpro Subcutaneous Solution 10 mg/1.5ml, 15 mg/1.5ml, 5 mg/1.5ml

Pending CMS review.

HARVONI

Drugs
Ledipasvir-Sofosbuvir Oral Tablet 90-400 mg

Exclusion Criteria
If administered with ribavirin, the contraindications to ribavirin also apply.

Required Medical Information
1. Diagnosis of hepatitis C. 2. Genotype. 3. Child Pugh Class. 4. Test patient for evidence of current or prior Hepatitis B Virus (HBV) infection before initiation treatment.

Age Restriction
3 years or older

Prescriber Restriction
None

Coverage Duration
12 to 24 weeks depending on baseline host and viral factors.

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

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

HEPSERA

Drugs
Adefovir Dipivoxil Oral Tablet 10 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of chronic hepatitis B.

Age Restriction
12 years or older

Prescriber Restriction
Gastroenterologist, Hepatologist or Infectious Disease Specialist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

HERNEXEOS

Drugs
Hernexeos 60 Mg Oral Tablet

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations. 2. Mutation confirmed by an FDA-approved test.

Age Restriction
18 years or older

Prescriber Restriction
Oncologist, Pneumologist and Pulmonologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

HETLIOZ

Drugs
Tasimelteon Oral Capsule 20 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of one of the following: A) Non-24-Hour Sleep Wake Disorder (Non-24). B) Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).

Age Restriction
For (Non-24): 18 years of age or older. For (SMS): 16 years of age or older.

Prescriber Restriction
Sleep Disorder Specialist, Neurologist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

HYFTOR

Drugs
Hyftor Gel 0.2 % External

Exclusion Criteria
None

Required Medical Information
Diagnosis of facial angiofibroma associated with tuberous sclerosis.

Age Restriction
6 years or older

Prescriber Restriction
Prescribed by or in consultation with a Dermatologist, Neurologist or Geneticist.

Coverage Duration
Initial: 3 months. Renewal: 12 months.

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

HYRNUO

Drugs
Hyrnuo Oral Tablet 10 MG

Exclusion Criteria
None

Required Medical Information
Diagnosis of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) in members whose tumors have HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.

Age Restriction
18 years of age or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

IBRANCE

Drugs
Ibrance Oral Capsule 125 mg
Ibrance Oral Tablet 75mg, 100 mg, 125 mg

Pending CMS review.

IBTROZI

Drugs
Ibtrozi Capsule 200 MG Oral

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of locally advanced or metastatic ROS1-positive non-small cell lung cancer. 2. Liver function tests (ALT, AST and bilirubin), electrolytes, ECG, and uric acid before treatment initiation.

Age Restriction
18 years or older

Prescriber Restriction
Oncologist, Pneumologist and Pulmonologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ICLUSIG

Drugs
Iclusig Oral Tablet 10 mg, 15 mg, 30 mg, 45 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: 1) Chronic Myeloid Leukemia (CML): A) Chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors, OR B) Accelerated phase (AP) or blast phase (BP) CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph ALL) for whom no other kinase inhibitors are indicated, OR C) T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL. Or 2) Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
Not recommended for the treatment of newly diagnosed chronic phase chronic myeloid leukemia (CP-CML).

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

IDHIFA

Drugs
Idhifa Oral Tablet 50 mg, 100 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA approved test.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

IMATINIB

Drugs
Imatinib Mesylate Oral Tablet 100 mg, 400 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis.

Age Restriction
1 year or older

Prescriber Restriction
Hematologist, Oncologist, Allergist, Immunologist, Dermatologist.

Coverage Duration
12 months

Other Criteria
For CML, new patient must have Ph-positive CML for approval of Imatinib. For ALL, new patient must have Ph-positive ALL for approval of Imatinib.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

IMBRUVICA

Drugs
Imbruvica Oral Capsule 70 mg, 140 mg
Imbruvica Oral Tablet 140 mg, 280 mg, 420 mg
Imbruvica Oral Suspension 70 mg/ml

Exclusion Criteria
None

Required Medical Information
1. Diagnosis. 2. Child-Pugh class. 3. Liver Function Test (LFT).

Age Restriction
None

Prescriber Restriction
Oncologist, Hematologist, Transplant Specialist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

IMKELDI

Drugs
Imkeldi Oral Solution 80 Mg/Ml

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
1 year or older

Prescriber Restriction
Hematologist, Oncologist, Allergist, Immunologist, Dermatologist, Gastroenterologist.

Coverage Duration
12 months

Other Criteria
For CML, new patient must have Ph-positive CML for approval of imatinib. For ALL, new patient must have Ph-positive ALL for approval of Imatinib.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

INBRIJA

Drugs
Inbrija Inhalation Capsule 42 mg

Pending CMS review.

INCRELEX

Drugs
Increlex Subcutaneous Solution 40 mg/4ml

Exclusion Criteria
1. Malignant neoplasia. 2. Closed epiphyses. 3. Intravenous administration.

Required Medical Information
1. Diagnosis of severe primary IGF-1 deficiency or growth hormone (GH) deletion who have developed neutralizing antibodies to GH. 2. Weight. 3. Laboratories confirmin: IGF-1 deficiency or growth hormone (GH) deletion. 4. Antibodies test.

Age Restriction
2-18 years old

Prescriber Restriction
Endocrinologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

INFLIXIMAB

Drugs
Zymfentra (2 Pen) Subcutaneous Auto-Injector Kit 120 MG/ML
Zymfentra (2 Syringe) Subcutaneous Prefilled Syringe Kit 120 MG/ML

Pending CMS review.

INLURIYO

Drugs
Inluriyo Oral Tablet 200 MG

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER2) negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

Age Restriction
18 years of age or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

INQOVI

Drugs
Inqovi Oral Tablet 35-100 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: A) myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups, or B) Newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy, to be used in combination with venetoclax. 2. Laboratories: CBC with differential.

Age Restriction
MDS: 18 years or older; AML: 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy.

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
Advise females of reproductive potential to use effective contraception during treatment with INQOVI and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with INQOVI and for 3 months after the last dose.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

INREBIC

Drugs
Inrebic Oral Capsule 100 mg

Exclusion Criteria
None

Required Medical Information
1.Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis. 2. Laboratories: CBC with differential, serum creatinine, liver function test (AST, ALT, bilirubin) and thiamine levels.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

INTERFERON BETA-1B

Drugs
Betaseron Subcutaneous Kit 0.3 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis. 2. MRI

Age Restriction
18 years or older

Prescriber Restriction
Neurologist or an MS specialist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

IRESSA

Drugs
Gefitinib Oral Tablet 250 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of 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 or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ITOVEBI

Drugs
Itovebi Oral Tablet 3 mg, 9mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or after completing adjuvant endocrine therapy. 2. To be used in combination with palbociclib and fulvestrant. 3. Mutation of PIK3CA confirmed by FDA-approved test.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

IWILFIN

Drugs
Iwilfin Oral Tablet 192 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of high-risk neuroblastoma (HRNB), to reduce the risk of relapse in patients that has demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.

Age Restriction
None

Prescriber Restriction
Hematologists, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

JAKAFI

Drugs
Jakafi Oral Tablet 5 mg, 10 mg, 15 mg, 20 mg, 25 mg
Jakafi XR Oral Tablet Extended Release 24 Hour 11 mg, 22 mg, 33 mg, 44 mg, 55 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) Intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. B) Polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea. C) Steroid-refractory acute graft-versus-host disease (aGVHD). D) Chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy.
2. Platelet count.

Age Restriction
For acute or chronic GVHD: 12 years or older. For MF or PV: 18 years or older.

Prescriber Restriction
Hematologist, Oncologist, Transplant Specialist.

Coverage Duration
Initial: 6 months. Renewal: 12 months.

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

JAYPIRCA

Drugs
Jaypirca Oral Tablet 50 mg, 100 mg

Pending CMS review.

JYDEYTRO

Drugs
Jideytro Oral Tablet 25 Mg, 100 Mg

Pending CMS review.

JOENJA

Drugs
Joenja Oral Tablet 70 Mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of f activated phosphoinositide 3-kinase delta syndrome (APDS).

Age Restriction
12 years or older

Prescriber Restriction
Allergist, Immunologist, Hematologist, Oncologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

JUXTAPID

Drugs
Juxtapid Oral Capsule 5 mg ,10 mg, 20 mg, 30 mg

Pending CMS review.

JYNARQUE

Drugs
Tolvaptan Oral Tablet, 15 MG, 30 MG
Tolvaptan Tablet Therapy Pack 15 MG Oral
Tolvaptan Tablet Therapy Pack 30 & 15 MG Oral
Tolvaptan Tablet Therapy Pack 45 & 15 MG Oral
Tolvaptan Tablet Therapy Pack 60 & 30 MG Oral
Tolvaptan Tablet Therapy Pack 90 & 30 MG Oral

Pending CMS review.

KALYDECO

Drugs
Kalydeco Oral Packet 25 mg, 50 mg, 75 mg
Kalydeco Oral Tablet 150 mg

Pending CMS review.

KESIMPTA

Drugs
Kesimpta Subcutaneous Solution Auto-Injector 20 mg/0.4ml

Exclusion Criteria
Active HBV infection.

Required Medical Information
Diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Age Restriction
18 years or older

Prescriber Restriction
Neurologist or MS Specialist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

KISQALI

Drugs
Kisqali 200 mg Dose Oral Tablet Therapy Pack
Kisqali 400 mg Dose Oral Tablet Therapy Pack
Kisqali 600 mg Dose Oral Tablet Therapy Pack

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: A) Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence, in combination with an aromatase inhibitor for the adjuvant treatment, OR B) HR-positive, HER2-negative advanced or metastatic breast cancer in combination with: an aromatase inhibitor as initial endocrine-based therapy, OR fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy. 2. Evaluate ECG prior to treatment initiation. Initiate treatment only in patients with QTcF smaller than 450 msec. 3. Liver function tests (LFTs) and complete blood count (CBC).

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

KOMZIFTI

Drugs
Komzifti Oral Capsule 200 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation who have no satisfactory alternative treatment options. 2. Serum potassium and magnesium within normal limits. 3. Baseline QTc interval.

Age Restriction
18 years and older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

KORLYM

Drugs
Mifepristone Oral Tablet 300 MG

Exclusion Criteria
None

Required Medical Information
1.Diagnosis of endogenous Cushings syndrome AND diagnosis of type 2 diabetes mellitus or glucose intolerance AND Patient has hyperglycemia secondary to hypercortisolism AND patient has failed or is not a candidate for surgery. 2. Member have failed or been intolerant to therapy with adrenal enzyme inhibitors.

Age Restriction
18 years or older

Prescriber Restriction
Endocrinologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

KOSELUGO

Drugs
Koselugo Oral Capsule 10 mg, 25 mg
Koselugo Oral Capsule Sprinkle 5 mg, 7.5 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of neurofibromastosis Type (NF1) who have symptomatic inoperable plexiform neurofibromas.

Age Restriction
1 year or older

Prescriber Restriction
Hematologist, Oncologist, Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

Drugs
Sapropterin Dihydrochloride Oral Packet 100 mg, 500 mg
Sapropterin Dihydrochloride Oral Tablet 100 mg

Pending CMS review.

LAZCLUZE

Drugs
Lazcluze Oral Tablet 80 mg, 240 mg

Exclusion Criteria
None

Required Medical Information
1) Diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations. 2) Mutation confirmed by FDA-approved test. 3) Medication is used in combination with amivantamab.

Age Restriction
18 years or older.

Prescriber Restriction
Oncologist, Pulmonologist, Pneumologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

LENVIMA

Drugs
Lenvima (4 MG Daily Dose) Capsule Therapy Pack 4 MG Oral
Lenvima (8 MG Daily Dose) Capsule Therapy Pack 2 x 4 MG Oral
Lenvima (10 MG Daily Dose) Capsule Therapy Pack 10 MG Oral
Lenvima (12 MG Daily Dose) Capsule Therapy Pack 3 x 4 MG Oral
Lenvima (14 MG Daily Dose) Capsule Therapy Pack 10 & 4 MG Oral
Lenvima (18 MG Daily Dose) Capsule Therapy Pack 10 MG & 2 x 4 MG Oral
Lenvima (20 MG Daily Dose) Capsule Therapy Pack 2 x 10 MG Oral
Lenvima (24 MG Daily Dose) Capsule Therapy Pack 2 x 10 MG & 4 MG Oral

Pending CMS review.

LEQEMBI

Drugs
Leqembi Iqlik Subcutaneous Solution Auto-Injector 360 MG/1.8ML

Pending CMS review.

LETAIRIS

Drugs
Ambrisentan Oral Tablet 5 mg, 10 mg

Exclusion Criteria
1. Pregnancy. 2. Idiopathic pulmonary fibrosis (IPF), including IPF patients with pulmonary hypertension (WHO Group 3).

Required Medical Information
1. Diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1): A) To improve exercise ability and delay clinical worsening. B) In combination with tadalafil, to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.

Age Restriction
18 years or older

Prescriber Restriction
Pulmonologist, Cardiologist

Coverage Duration
Initial: 6 months. Renewal: 12 months.

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

LEUKINE

Drugs
Leukine Solution Reconstituted 250 MCG Injection

Exclusion Criteria
None

Required Medical Information
1) Diagnosis of one of the following: a) Patient has undergone allogeneic or autologous bone marrow transplant (BMT) and engraftment is delayed or failed, b) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, c) Medication will be used for myeloid reconstitution after an autologous or allogeneic BMT, d) Patient has acute myeloid leukemia and administration will be after completion of induction chemotherapy, e) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS) or f) Autologous peripheral blood stem cell transplant, following myeloablative chemotherapy. 2) Body weight and height.

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist, Neurologist or Infectious Disease Specialist.

Coverage Duration
6 months

Other Criteria
Subject to BvsD review. For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

LEUPROLIDE (LHRH)

Drugs
Eligard Kit Subcutaneous 7.5 MG, 22.5 MG, 30 MG, 45 MG
Leuprolide Acetate KIT Injection 1 MG/0.2ML
Lupron Depot (1-Month) KIT 3.75 MG Intramuscular
Lupron Depot (1-Month) Kit 7.5 MG Intramuscular
Lupron Depot (3-Month) KIT 11.25 MG Intramuscular
Lupron Depot (3-Month) Kit 22.5 MG Intramuscular
Lupron Depot (4-Month) Kit 30 MG Intramuscular
Lupron Depot (6-Month) Kit 45 MG Intramuscular

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Gynecologist, Urologist, Oncologist, Endocrinologist

Coverage Duration
12 months

Other Criteria
Subject to B vs D review, except for leuprolide 5mg/mL.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

LIFYORLI

Drugs
Lifyorli (125 MG DOSE) Capsule Therapy Pack 1 x 25 MG & 1 x 100 MG Oral (1-DOSE SUPPLY)
Lifyorli (125 MG DOSE) Capsule Therapy Pack 1 x 25 MG & 1 x 100 MG Oral (3-DOSE SUPPLY)
Lifyorli (125 MG DOSE) Capsule Therapy Pack 1 x 25 MG & 1 x 100 MG Oral (9-DOSE SUPPLY)
Lifyorli (150 MG DOSE) Capsule Therapy Pack 2 x 25 MG & 1 x 100 MG Oral (1-DOSE SUPPLY)
Lifyorli (150 MG DOSE) Capsule Therapy Pack 2 x 25 MG & 1 x 100 MG Oral (3-DOSE SUPPLY)
Lifyorli (150 MG DOSE) Capsule Therapy Pack 2 x 25 MG & 1 x 100 MG Oral (9-DOSE SUPPLY)

Exclusion Criteria
Concurrent systemic glucocorticoid therapy for a lifesaving indication.

Required Medical Information
Diagnosis of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, in combination with nab-paclitaxel, who have received one to three prior systemic treatment regimens, at least one of which included bevacizumab.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Gynecologic Oncologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

LINEZOLID

Drugs
Linezolid Oral Tablet 600 mg
Linezolid Oral Suspension Reconstituted 100 mg/5ml
Linezolid Intravenous Solution 600 mg/300ml

Pending CMS review.

LIRAGLUTIDE (GLP-1)

Drugs
Liraglutide Solution Pen-Injector 18 MG/3ML Subcutaneous

Exclusion Criteria
Personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine. Neoplasia syndrome type 2 (MEN 2).

Required Medical Information
1. Diagnosis of one of the following: A) Type 2 diabetes mellitus for glycemic control or B) Type 2 diabetes mellitus with established cardiovascular disease, to reduce the risk of major adverse cardiovascular event. 2. A1C.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

LIVTENCITY

Drugs
Livtencity Oral Tablet 200 Mg

Pending CMS review.

LORAZEPAM (HRM)

Drugs
Lorazepam Intensol Concentrate 2 MG/ML Oral
Lorazepam Oral Tablet 0.5 MG, 1 MG, 2 MG

Pending CMS review.

LORBRENA

Drugs
Lorbrena Oral Tablet 25 mg, 100 mg

Exclusion Criteria
Concomitant use with strong CYP3A inducers.

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

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

LOTRONEX

Drugs
Alosetron HCl Oral Tablet 0.5 mg, 1 mg

Exclusion Criteria
Do not initiate in patients with constipation. History of chronic or severe constipation or sequelae from constipation, intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions. Ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state. Crohn's disease or ulcerative colitis, diverticulitis, severe hepatic impairment, concomitant use of fluvoxamine.

Required Medical Information
Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) in women. Child-Pugh Score.

Age Restriction
18 years or older

Prescriber Restriction
Gastroenterologist

Coverage Duration
Initial: 6 months. Renewal: 12 months.

Other Criteria
Medication only approved for women, not for use in men. For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

LUMAKRAS

Drugs
Lumakras Oral Tablet 120 mg, 240 mg, 320 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of one of the following: 1) KRAS G12C-mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC), as determined by an FDA-approved test, member has received at least one prior systemic therapy, AND Lumakras (sotorasib) will be used as a single agent, OR 2) KRAS G12C-mutated Metastatic Colorectal Cancer (mCRC), as determined by an FDA-approved test, member has received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, AND Lumakras (sotorasib) will be used in combination with panitumumab.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

LUMRYZ

Drugs
Lumryz Oral Packet 4.5 gm, 6 gm, 7.5 gm, 9 gm
Lumryz Starter Pack Oral Therapy Pack 4.5 & 6 & 7.5 gm

Exclusion Criteria
1. Concomitant use of sedative hypnotics. 2. Patient with succinic semialdehyde dehydrogenase deficiency.

Required Medical Information
1. Diagnosis of cataplexy or excessive daytime sleepiness (EDS) with narcolepsy. 2. Diagnosis were confirmed by sleep evaluation (e.g. multiple sleep latency test, polysomnography). 3. For adults patients with excessive daytime sleepiness, patient had a previous trial or has a contraindication, intolerance or allergy to modafinil, armodafinil, methylphenidate, dextroamphetamine, or mixed amphetamine salts.

Age Restriction
7 years of age and older

Prescriber Restriction
None

Coverage Duration
Initial: 6 months. Renewal: 12 months.

Other Criteria
For renewal, the member had a positive response to the medication (increased sleep quality) and has not experienced any serious adverse events while on medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

LYNPARZA

Drugs
Lynparza Oral Tablet 100 mg, 150 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of ovarian, breast, pancreatic or prostate cancer.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

LYTGOBI

Drugs
Lytgobi (12 mg Daily Dose) Oral Tablet Therapy Pack 4 mg
Lytgobi (16 mg Daily Dose) Oral Tablet Therapy Pack 4 mg
Lytgobi (20 mg Daily Dose) Oral Tablet Therapy Pack 4 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Gastroenterologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

MAVYRET

Drugs
Mavyret Oral Tablet 100-40 mg

Exclusion Criteria
Coadministration with atazanavir and rifampin. Patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation.

Required Medical Information
1. Diagnosis of Hepatitis C virus (HCV). 2. Treatment status of patient (treatment naive or treatment experienced). 3. Cirrhosis status. 4. Hepatitis B status

Age Restriction
3 years or older

Prescriber Restriction
None

Coverage Duration
8 to 16 weeks

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

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

MAYZENT

Drugs
Mayzent Starter Pack Oral Tablet Therapy Pack 7 X 0.25 mg
Mayzent Starter Pack Oral Tablet Therapy Pack 12 X 0.25 mg
Mayzent Oral Tablet 0.25 mg, 1 mg, 2 mg

Exclusion Criteria
1. Patients with a CYP2C9*3/*3 genotype. 2. In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure. 3. Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker.

Required Medical Information
Diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Age Restriction
18 years or older

Prescriber Restriction
Neurologist, Multiple Sclerosis Specialist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

MEGESTROL

Drugs
Megestrol Acetate Oral Suspension 40 mg/ml
Megestrol Acetate Oral Suspension 625 mg/5ml
Megestrol Acetate Oral Tablet 20 mg, 40mg

Exclusion Criteria
Pregnancy

Required Medical Information
Megestrol Oral Suspension: Diagnosis of one anorexia, cachexia, or an unexplained significant weight loss in patients with a diagnosis of acquired immunodeficiency syndrome (AIDS). Megestrol Oral Tablets: Diagnosis of one of the following: 1. Advanced, inoperable, recurrent metastatic breast cancer OR 2. Advanced, inoperable, recurrent metastatic endometrial cancer.

Age Restriction
18 years or older

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

MEPRON

Drugs
Atovaquone Oral Suspension 750 mg/5ml

Exclusion Criteria
None

Required Medical Information
Diagnosis of mild-to-moderate Pneumocystis pneumonia (PCP) and drug will be used for either treatment or PCP prophylaxis.

Age Restriction
13 years and older

Prescriber Restriction
Infectious Disease specialist

Coverage Duration
12 months

Other Criteria
For patients that cannot tolerate trimethoprimsulfamethoxazole (TMP-SMX). For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

METHYLNALTREXONE

Drugs
Relistor Solution Prefilled Syringe 12 MG/0.6ML SubcutaneousRelistor Solution Prefilled Syringe 8 MG/0.4ML Subcutaneous
Relistor Subcutaneous Solution 12 mg/0.6ml

Exclusion Criteria
Known or suspected mechanical gastrointestinal obstruction and patients at an increased risk of recurrent obstruction, gastrointestinal perforation may occur.

Required Medical Information
Diagnosis of opioid induced constipation. Trial and failure of a laxative in the past 90 days.

Age Restriction
18 years or older

Prescriber Restriction
Gastroenterologist, Oncologist, Hematologist, Pain Management Specialist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

MODAFINIL

Drugs
Modafinil Oral Tablet 100 mg 200 mg

Pending CMS review.

MODEYSO

Drugs
Modeyso Capsule 125 MG Oral

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy.

Age Restriction
1 year of age and older

Prescriber Restriction
Oncologist, Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

NAYZILAM

Drugs
Nayzilam Nasal Solution 5 mg/0.1ml

Exclusion Criteria
Patients with acute narrow-angle glaucoma.

Required Medical Information
1. Diagnosis of stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures)
2. Physician must certify that episodes are distinct from patients' usual seizure pattern.

Age Restriction
12 years or older

Prescriber Restriction
Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

NERLYNX

Drugs
Nerlynx Oral Tablet 40 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) As a single agent, for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy. B) In combination with capecitabine, for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

NEXAVAR

Drugs
Sorafenib Tosylate Oral Tablet 200 mg

Exclusion Criteria
Combination with carboplatin and paclitaxel in patients with squamous cell lung cancer.

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

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

NINLARO

Drugs
Ninlaro Oral Capsule 2.3 mg, 3 mg, 4 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis: use with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. 2. Previous Therapy 3. Protocol- to be use with lenalidomide and dexamethasone. 4. CBC (diferential), serum creatinine and total bilirubin. 5. Pregnancy status for females of reproductive potential.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
Prior to initiating a new cycle of therapy: Absolute neutrophil count should be at least 1,000/mm3, Platelet count should be at least 75,000/mm3.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

NITISINONE

Drugs
Nityr Oral Tablet 2 mg, 5 mg, 10 mg
Nitisinone Oral Capsule 2 mg, 5 mg, 10 mg, 20 mg
Orfadin Oral Suspension 4 mg/ml

Pending CMS review.

NORTHERA

Drugs
Droxidopa Oral Capsule 100 mg, 200 mg, 300 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of neurogenic orthostatic hypotension (NOH), caused by primary autonomic failure (e.g. Parkinsons disease, multiple system atrophy, or pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy.

Age Restriction
18 years or older

Prescriber Restriction
None

Coverage Duration
2 weeks

Other Criteria
Effectiveness beyond 2 weeks of treatment has not been established.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

NUBEQA

Drugs
Nubeqa Oral Tablet 300 Mg

Pending CMS review.

NUCALA

Drugs
Nucala Subcutaneous Solution Reconstituted 100 mg
Nucala Subcutaneous Solution Auto-Injector 100 mg/ml
Nucala Subcutaneous Solution Prefilled Syringe 100 mg/ml

Pending CMS review.

NUEDEXTA

Drugs
Nuedexta Oral Capsule 20-10 mg

Pending CMS review.

NUPLAZID

Drugs
Nuplazid Oral Tablet 10 mg
Nuplazid Oral Capsule 34 mg

Exclusion Criteria
Elderly patients with dementia-related psychosis.

Required Medical Information
Diagnosis of hallucinations and delusions associated with Parkinsons disease psychosis.

Age Restriction
18 years or older

Prescriber Restriction
Psychiatrist, Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

Drugs
Armodafinil Oral Tablet 50 mg, 150 mg, 200 mg, 250 mg

Pending CMS review.

NUZYRA

Drugs
Nuzyra Solution Reconstituted 100 MG Intravenous
Nuzyra Tablet 150 MG Oral

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: a) Community-acquired bacterial pneumonia (CABP) or b) Acute bacterial skin and skin structure infections (ABSSSI). 2. Culture. 3. The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least one alternative from a class of antibiotics used to treat the submitted diagnosis. For CABP: amoxicillin, doxycycline or macrolide, For ABSSSI: cephalexin, dicloxacillin, clindamycin, doxycycline, OR the physician submits clinical rationale as to why these agents would not be appropriate for the patient.

Age Restriction
18 years or older

Prescriber Restriction
Pulmonologist, Pneumologist, Infectious Disease Physician, Dermatologist

Coverage Duration
14 days

Other Criteria
Nuzyra will be authorized for patients who have initiated oral or intravenous therapy in a hospital and are discharged to complete the course of therapy.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

ODOMZO

Drugs
Odomzo Oral Capsule 200 mg

Exclusion Criteria
Pregnancy

Required Medical Information
Diagnosis of locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

OFEV

Drugs
Nintedanib Esylate Oral Capsule 100 mg, 150 mg
Ofev Oral Capsule 100 MG; 150 MG

Exclusion Criteria
Pregnancy

Required Medical Information
1. Diagnosis of one of the following, a) Idiopathic pulmonary fibrosis confirmed by a high resolution CT scan or biopsy, OR b) Decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD), OR c) Diagnosis of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype. 2. Liver function tests have been performed prior to start of therapy. 3. Pregnancy test in females of reproductive potential prior to initiation.

Age Restriction
18 years or older

Prescriber Restriction
Pulmonologist or Rheumatologist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

OGSIVEO

Drugs
Ogsiveo Oral Tablet 100 MG, 150 MG

Exclusion Criteria
None

Required Medical Information
Diagnosis of progressing desmoid tumors who require systemic treatment.

Age Restriction
18 years or older

Prescriber Restriction
Hematologists, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

OJEMDA

Drugs
Ojemda Oral Suspension Reconstituted 25 MG/ML
Ojemda Oral Tablet 100 MG
Ojemda Oral Tablet 100 MG (16 pack)
Ojemda Oral Tablet 100 MG (24 pack)

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of relapsed or refractory pediatric lowgrade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. 2. Confirmation of the presence of BRAF fusion or rearrangement or BRAF V600 mutation as detected by an FDA approved test. 3. Body Surface Area (BSA).

Age Restriction
6 months of age and older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

OJJAARA

Drugs
Ojjaara Oral Tablet 100 MG, 150 MG, 200MG

Exclusion Criteria
None

Required Medical Information
Diagnosis of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post polycythemia vera (PV) and post-essential thrombocythemia (ET)], in patients with anemia.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Immunologist, Transplant Specialist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

OPSUMIT

Drugs
Macitentan Oral Tablet 10 mg

Exclusion Criteria
Pregnancy

Required Medical Information
1. Diagnosis of pulmonary artery hypertension as defined by WHO group 1 and confirmed by right heart catheterization. 2. Baseline liver enzymes.3. CBC

Age Restriction
18 years or older

Prescriber Restriction
Pulmonologist, Cardiologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

OPSYNVI

Drugs
Opsynvi Oral Tablet 10-20 mg, 10-40 mg

Pending CMS review.

ORKAMBI

Drugs
Orkambi Oral Tablet 100-125 mg, 200-125 mg
Orkambi Oral Packet 75-94 mg, 100-125 mg, 150-188 mg

Pending CMS review.

ORLADEYO

Drugs
Orladeyo Oral Capsule 110 mg, 150 mg

Pending CMS review.

ORSERDU

Drugs
Orserdu Oral Tablet 86 mg, 345 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER2) negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy in postmenopausal women or adult men.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

OTEZLA

Drugs
Otezla Oral Tablet 20 mg, 30 mg
Otezla Oral Tablet Therapy Pack 10 & 20 & 30 mg
Otezla Oral Tablet Therapy Pack 4 x 10 & 51 x20 mg
Otezla XR Oral Tablet Extended Release 24 Hour 75 mg
Otezla/Otezla XR Initiation Pk Oral Tablet Therapy Pack 10&20&30&(ER)75 mg

Exclusion Criteria
None

Required Medical Information
1.Diagnosis of any of the following: (A)active psoriatic arthritis (PsA), (B) plaque psoriasis who are candidates for phototherapy or systemic therapy, OR (C) oral ulcers associated with Behcets Disease. 2.For Plaque Psoriasis (New starts ONLY), patient meets any of the following: (A) inadequate response or intolerance to ONE of the following: (1) a Topical Therapy (e.g., Topical corticosteroid, calcineurin inhibitor, Vitamin D analog), (2) Phototherapy (e.g., UVB, PUVA), OR (3) Pharmacologic treatment with methotraxate, cyclosporine or acitretin OR (3) Pharmacologic treatment with methotrexate or acitretin is contraindicated. 4. Serum creatinine or creatinine clearance.

Age Restriction
For oral ulcers: 18 years or older. For PsA and plaque psoriasis: 6 years of age and older and weighing at least 20 kg.

Prescriber Restriction
Rheumatologist, Dermatologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

Drugs
Prolastin-C Intravenous Solution Reconstituted 1000 mg

Exclusion Criteria
Immunoglobulin A (IgA) deficient patients with antibodies against IgA.

Required Medical Information
Diagnosis of emphysema due to severe hereditary deficiency of alpha1-antitrypsin (Alpha1-PI) as part of chronic augmentation and maintenance treatment.

Age Restriction
18 years or older

Prescriber Restriction
Pulmonologist, Geneticist

Coverage Duration
12 months

Other Criteria
Subject to B vs D review. For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

PANRETIN

Drugs
Panretin External Gel 0.1 %

Exclusion Criteria
None

Required Medical Information
Diagnosis of AIDS-related Kaposi sarcoma.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Infectologist, Dermatologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

PEGASYS

Drugs
Pegasys Subcutaneous Solution Prefilled Syringe 180 Mcg/0.5ml
Pegasys Subcutaneous Solution 180 Mcg/ml

Exclusion Criteria
Autoimmune hepatitis. Hepatic decompensation (Child-Pugh score greater than 6 [class B and C]) in cirrhotic patients before treatment. Hepatic decompensation with Child-Pugh score greater than or equal to 6 in cirrhotic CHC patients coinfected with HIV before treatment. Hypersensitivity reactions such as urticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome to alpha interferons or any of its components.

Required Medical Information
Diagnosis of, 1. chronic hepatitis B OR 2. chronic Hepatitis C.

Age Restriction
HCV: 18 years of age or older if using triple therapy (Pegasys + antiviral + RBV), other regimens: 5 years of age or older. HBV: 3 years of age or older.

Prescriber Restriction
Infectious disease physician, gastroenterologist, hepatologist, or a transplant physician

Coverage Duration
48 weeks

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

PEMAZYRE

Drugs
Pemazyre Oral Tablet 13.5 mg, 4.5 mg, 9 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: A) 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, OR B) relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth factor receptor 1 (FGFR1) rearrangement.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

PHEBURANE

Drugs
Pheburane Oral Pellet 483 mg/gm

Exclusion Criteria
None

Required Medical Information
Diagnosis of urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthethase (CPS), ornithine transcarbamylase (OTC) or arginosuccinic acid synthetase (AS).

Age Restriction
None

Prescriber Restriction
Prescribed by or in consultation with a geneticist or hepatologist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Drugs
Sildenafil Citrate Oral Suspension Reconstituted 10 mg/ml
Sildenafil Citrate Oral Tablet 20 mg

Exclusion Criteria
1. Use for erectile dysfunction. 2. Patients taking nitrates. 3. Patients taking Guanylate Cyclase (GC) Stimulators.

Required Medical Information
Diagnosis of any of the following: A) Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) confirmed by right hearth catheterization to improve exercise ability and delay clinical worsening, in adults patients. B) Pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and, in pediatric patients too young to perform standard exercise testing, pulmonary hemodynamics thought to underlie improvements in exercises.

Age Restriction
None

Prescriber Restriction
Pulmonologist, Cardiologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

PIQRAY

Drugs

Piqray (200 mg Daily Dose) Oral Tablet Therapy Pack 200 mg
Piqray (250 mg Daily Dose) Oral Tablet Therapy Pack 200 & 50 mg
Piqray (300 mg Daily Dose) Oral Tablet Therapy Pack 2 X 150 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

POMALIDOMIDE

Drugs
Pomalyst Oral Capsule 1 mg, 2 mg, 3 mg, 4 mg

Pending CMS review.

PRETOMANID

Drugs
Pretomanid Oral Tablet 200 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB), 2. To be used in combination with bedaquiline and linezolid, 3. Baseline test: ECGs, liver function, CBC.

Age Restriction
18 years or older

Prescriber Restriction
Infectious Disease, TB Specialist or Pneumologist

Coverage Duration
26 weeks

Other Criteria
Pretomanid is not recommended for the treatment of drug-sensitive TB, latent infection due to Mycobacterium TB, for the treatment of extrapulmonary TB (eg, CNS), or for the treatment of non-tuberculous mycobacterial infections.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

PREVYMIS

Drugs
Prevymis Oral Tablet 240 mg, 480 mg

Exclusion Criteria
Patients receiving concomitant: Orap (pimozide) or ergot alkaloids, patients receiving concomitant Livalo (pitavastatin) or Zocor (simvastatin) when co-administered with cyclosporine.

Required Medical Information
Diagnosis of any of the following: A) Cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT), and drug will be used for prophylaxis. B) CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]), and drug will be used for prophylaxis.

Age Restriction
6 months of age and older.

Prescriber Restriction
Hematologist, Oncologist, Infectious Disease Specialist or Transplant Specialist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

Drugs
Bildyos Subcutaneous Solution Prefilled Syringe 60 Mg/Ml

Pending CMS review.

PROMACTA

Drugs
Eltrombopag Olamine Packet 12.5 MG Oral
Eltrombopag Olamine Packet 25 MG Oral
Eltrombopag Olamine Tablet 12.5 MG Oral
Eltrombopag Olamine Tablet 25 MG Oral
Eltrombopag Olamine Tablet 50 MG Oral
Eltrombopag Olamine Tablet 75 MG Oral

Pending CMS review.

PYLERA

Drugs
Pylera Oral Capsule 140-125-125 MG

Pending CMS review.

PYRIMETHAMINE

Drugs
Pyrimethamine Oral Tablet 25 Mg

Exclusion Criteria
Megaloblastic anemia due to folate deficiency.

Required Medical Information
Diagnosis of Toxoplasmosis and treatment in combination with a sulfonamide.

Age Restriction
None

Prescriber Restriction
Infectious Disease Specialist or Transplant Specialist

Coverage Duration
6 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and ((2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

PYRUKYND

Drugs

Pyrukynd Oral Tablet 5 Mg, 20 Mg, 50 Mg
Pyrukynd Taper Pack Oral Tablet Therapy Pack 5 mg
Pyrukynd Taper Pack Oral Tablet Therapy Pack 7 X 20 mg & 7 X 5 mg
Pyrukynd Taper Pack Oral Tablet Therapy Pack 7 X 50 mg & 7 X 20 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of hemolytic anemia in adults with pyruvate kinase (PK) deficiency. 2. Patient must have hemoglobin less than or equal 10 g/dL or receives regular blood transfusions (at least 6 in the past year). 3. Laboratory test confirming pyruvate kinase (PK) deficiency.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

QINLOCK

Drugs
Qinlock Oral Tablet 50 Mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

Age Restriction
18 years or older.

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

QULIPTA

Drugs
Qulipta Oral Tablet 10 mg, 30mg, 60mg

Pending CMS review.

Drugs
Radicava Ors Starter Kit Oral Suspension 105 Mg/5ml

Pending CMS review.

RALDESY

Drugs
Raldesy Oral Solution 10 mg/ml

Exclusion Criteria
Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of stopping MAOIs

Required Medical Information
Diagnosis of major depressive disorder (MDD).

Age Restriction
18 years and older

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

RAVICTI

Drugs
Glycerol Oral Phenylbutyrate Liquid 1.1 GM/ML

Exclusion Criteria
None

Required Medical Information
Diagnosis of urea cycle disorders (UCDs) and drug will be used as part of the chronic management.

Age Restriction
None

Prescriber Restriction
Urea Cycle Disorder Specialist, Metabolic Disorder Specialist

Coverage Duration
12 months

Other Criteria
Not indicated for the treatment of acute hyperammonemia in patients with UCDs and for the treatment of N-acetylglutamate synthase. For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

RECORLEV

Drugs
Recorlev Oral Tablet 150 Mg

Exclusion Criteria
1. Cirrhosis, acute liver disease or poorly controlled chronic liver disease, AST or ALT more than three times upper limit normal, recurrent symptomatic cholelithiasis, a prior history of drug induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation. 2. Concomitant use of drugs that causes QT prolongation associated with ventricular arrhythmias, including torsades de pointes. 3. Prolonged QTcF interval more than 470 milliseconds at baseline, torsade de pointes, ventricular tachycardia, ventricular fibrillation, or prolonged QT syndrome.

Required Medical Information
1. Diagnosis of (pituitary) Cushings disease AND pituitary surgery is not an option or has not been curative. 2. Baseline 24-hour urine free cortisol level equal or higher than 1.5 x upper limit of normal.

Age Restriction
18 years or older

Prescriber Restriction
Endocrinologist

Coverage Duration
12 months

Other Criteria
For continuation: 24-hour urine free cortisol level shows improvement in urinary free cortisol levels AND patient is tolerating treatment.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

REGORAFENIB

Drugs
Stivarga Oral Tablet 40 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

RELUGOLIX

Drugs
Orgovyx Oral Tablet 120 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist, Urologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

RETEVMO

Drugs
Retevmo Oral Tablet 40 mg, 80mg, 120 mg, 160 mg

Exclusion Criteria
None

Required Medical Information
1.Diagnosis of any of the following: A) Locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test, B) Advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy, C) Advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate), D) Locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. 2. Weight 3. Pregnancy test for women of reproductive potential. 4. Liver function test (AST, ALT, bilirubin).

Age Restriction
For non-small cell lung cancer: 18 years or older. For solid tumor, medullary thyroid cancer or thyroid cancer: 2 years of age and older.

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

REVCOVI

Drugs
Revcovi Solution 2.4 MG/1.5ML Intramuscular

Pending CMS review.

REVUFORJ

Drugs
Revuforj Oral Tablet 25 Mg, 110 Mg, 160 Mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of one of the following: a) relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation AND presence of a KMT2A translocation was confirmed by an FDA-authorized test OR, b) relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation, in patients who have no satisfactory alternative treatment options.

Age Restriction
1 year or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

REZDIFFRA

Drugs
Rezdiffra Tablet 60 MG, 80 MG, 100 MG Oral

Pending CMS review.

REZLIDHIA

Drugs
Rezlidhia Oral Capsule 150 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with susceptible IDH1 mutation as detected by an FDA approved test.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

REZUROCK

Drugs
Rezurock Oral Tablet 200 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of chronic graft-versus-host disease (chronic GVHD) and member has failed at least two prior lines of systemic therapy. 2. Liver function test (ALT, AST and bilirubin).

Age Restriction
12 years or older

Prescriber Restriction
Oncologist, Hematologist, Transplant Specialist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

Drugs
Riluzole Oral Tablet 50 mg

Pending CMS review.

RINVOQ

Drugs
Rinvoq Oral Tablet Extended Release 24 Hour 15 mg, 30 mg, 45 mg

Pending CMS review.

ROMVIMZA

Drugs
Romvimza Oral Capsule 14 mg, 20 mg, 30 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.

Age Restriction
18 years or older

Prescriber Restriction
Oncologist, Orthopedic Oncologist, Rheumatologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ROZLYTREK

Drugs
Rozlytrek Oral Capsule 100 mg, 200 mg
Rozlytrek Oral Packet 50 MG

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: A) Metastatic non-small cell lung cancer (NSCLC) AND tumors are ROS1-positive, as detected by an FDA-approved test. B) Solid tumors that: i) have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, as detected by an FDA-approved test without a known acquired resistance mutation, AND ii) are metastatic or where surgical resection is likely to result in severe morbidity, AND iii) have progressed following treatment or have no satisfactory alternative therapy.

Age Restriction
For NSCLC: 18 years or older. For Solid tumors: 1 month of age or older.

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

RUBRACA

Drugs
Rubraca Oral Tablet 200 mg, 250 mg, 300 mg

Pending CMS review.

RYDAPT

Drugs
Rydapt Oral Capsule 25 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: 1. Newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by an FDA-approved test, 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
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Allergist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

SABRIL

Drugs
Vigabatrin Oral Packet 500 mg
Vigabatrin Oral Tablet 500 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: 1) Refractory Complex Partial Seizures (CPS), for use as adjunctive therapy and patient responded inadequately, has contraindication or intolerance to two formulary anticonvulsants (eg, lamotrigine, valproic acid, phenytoin), OR 2) Infantile Spasms (IS).

Age Restriction
CPS: 2 years of age and older. IS: 1 month to 2 years of age.

Prescriber Restriction
Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

SCEMBLIX

Drugs
Scemblix Oral Tablet 20 mg, 40 mg, 100 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: a) Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), or b) Previously treated Ph+ CML in CP, or c) Ph+ CML in CP with the T315I mutation.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Immunologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

SEMAGLUTIDE (GLP-1)

Drugs
Ozempic (0.25 or 0.5 MG/DOSE) Subcutaneous Solution Pen-Injector 2 mg/3ml
Ozempic (1 MG/DOSE) Subcutaneous Solution Pen-Injector 4 mg/3ml
Ozempic (2 MG/DOSE) Subcutaneous Solution Pen-Injector 8 mg/3ml
Ozempic Oral Tablet 1.5 mg, 4 mg, 9 mg
Wegovy Subcutaneous Solution Auto-Injector 0.25 mg/0.5ml, 0.5 mg/0.5ml, 1mg/0.5ml, 1.7mg/0.75ml, 2.4mg/0.75ml
Wegovy Oral Tablet 1.5 mg, 4mg, 9mg, 25mg

Pending CMS review.

SIGNIFOR

Drugs
Signifor Subcutaneous Solution 0.3 mg/ml, 0.6 mg/ml, 0.9 mg/ml

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of (pituitary) Cushings disease AND pituitary surgery is not an option or has not been curative. 2. Baseline 24-hour urine free cortisol level equal or higher than 1.5 x upper limit of normal. 3.Failure of at least one prior agent used in the treatment of Cushings disease (ketoconazole, mitotane, or metyrapone) or contraindication to all agents. 4. Liver function test.

Age Restriction
18 years or older

Prescriber Restriction
Endocrinologist

Coverage Duration
12 months

Other Criteria
For continuation: 24-hour urine free cortisol level shows improvement in urinary free cortisol levels AND patient is tolerating treatment.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

SIRTURO

Drugs
Sirturo Oral Tablet 20 mg, 100 mg

Pending CMS review.

SKYCLARYS

Drugs
Skyclarys Oral Capsule 50 mg

Pending CMS review.

SKYRIZI

Drugs
Skyrizi Subcutaneous Pen Solution Auto-Injector 150 mg/ml
Skyrizi Subcutaneous Solution Prefilled Syringe 55 mg/0.37ml, 150 mg/ml
Skyrizi Subcutaneous Solution Cartridge 180 mg/1.2ml, 360 mg/2.4ml

Pending CMS review.

SOMAVERT

Drugs
Somavert Subcutaneous Solution Reconstituted 10 mg, 15 mg, 20 mg, 25 mg, 30 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of Acromegaly.

Age Restriction
18 years or older

Prescriber Restriction
Endocrinologist

Coverage Duration
12 months

Other Criteria
Patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum IGF-I levels.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

Drugs
Dasatinib Oral Tablet 20 mg, 50mg, 70mg, 80mg, 100 mg, 140 mg

Pending CMS review.

SUTENT

Drugs
Sunitinib Malate Oral Capsule 12.5 mg, 25 mg, 37.5 mg, 50 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: 1) treatment of adult patients with gastrointestinal stromal tumors (GIST) after disease progression and or intolerance to imatinib mesylate. 2) treatment of adult patients with advance renal cell carcinoma (RCC) or adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy. 3) treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in adult patients with unresectable locally advanced or metastatic disease. 2. Liver function tests

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

SYNAREL

Drugs
Synarel Nasal Solution 2 mg/ml

Exclusion Criteria
Pregnancy, breast feeding, abnormal vaginal bleeding.

Required Medical Information
Diagnosis of any of the following: A) Central Precocious Puberty (CPP). B) Endometriosis, including pain relief and reduction of endometriotic lesions.

Age Restriction
None

Prescriber Restriction
Gynecologist, Endocrinologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TABRECTA

Drugs
Tabrecta Oral Tablet 150 mg, 200 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TADALAFIL

Drugs
Tadalafil Oral Tablet 5 Mg

Exclusion Criteria
Any of the following A.) concurrent use of nitrates, including intermittent use, or B.) diagnosis of erectile dysfunction without signs and symptoms of BPH.

Required Medical Information
1. Diagnosis of benign prostatic hyperplasia (BPH). 2. Member has tried and has treatment failure to one (1) alpha-blocker for example: doxazosin, prazosin, silodosin, terazocin, tamsulosin AND one (1) 5-alpha reductase inhibitor, for example: dutasteride, finasteride) OR has experienced intolerance.

Age Restriction
None

Prescriber Restriction
Urologist

Coverage Duration
12 months

Other Criteria
For renewal, patient has stable disease or has improved while on therapy.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

TAGRISSO

Drugs
Tagrisso Oral Tablet 40 mg, 80 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis for one of the following indications: 1) as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. 2) locally advanced, unresectable (stage III) NSCLC whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. 3) as first-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. 4) in combination with pemetrexed and platinum-based chemotherapy, the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. OR 5) treatment of patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy (Afatinib (Giotrif),Axitinib (Inlyta),Bosutinib (Bosulif),Crizotinib (Xalkori),Dasatinib (Sprycel),Erlotinib (Tarceva),Gefitinib (Iressa),Imatinib (Gleevec),Lapatinib (Tyverb),Nilotinib (Tasigna),Pazopanib (Votrient),Regorafenib (Stivarga),Sorafenib (Nexavar),Sunitinib (Sutent)).

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

TAKHZYRO

Drugs
Takhzyro Subcutaneous Solution Prefilled Syringe 300 mg/2ml

Exclusion Criteria
None

Required Medical Information
Diagnosis of hereditary angioedema AND For long-term prophylaxis treatment to prevent attacks of hereditary angioedema (HAE).

Age Restriction
2 years or older

Prescriber Restriction
Immunologist, Allergist, Rheumatologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TALZENNA

Drugs
Talzenna Oral Capsule 0.1 mg, 0.25 mg, 0.35 mg, 0.5 mg, 0.75 mg, 1 mg

Pending CMS review.

TAMOXIFEN

Drugs
Soltamox Oral Solution 10 mg/5ml

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TARCEVA

Drugs
Erlotinib Oral Tablet 25 mg, 100 mg, 150 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: A) 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 receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. B) First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

TARGRETIN

Drugs
Bexarotene External Gel 1 %
Bexarotene Oral Capsule 75 mg

Pending CMS review.

TARPEYO

Drugs
Tarpeyo Oral Capsule Delayed Release 4 MG

Pending CMS review.

TASIGNA

Drugs
Nilotinib Hcl Oral Capsule 150 mg, 200 mg, 50 mg

Exclusion Criteria
Hypokalemia, hypomagnesemia, long QT syndrome.

Required Medical Information
Indicated for the treatment of any of the following: 1. Adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase, OR 2. Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ is resistant to or intolerant to prior therapy that included imatinib, OR 3. Pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP and CML-AP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
For CML, new patient must have Ph-positive CML for approval of nilotinib.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

TAVNEOS

Drugs
Tavneos Oral Capsule 10 mg

Pending CMS review.

TAZORAC

Drugs
Tazarotene External Cream 0.05 %, 0.1 %
Tazarotene External Gel 0.05 %, 0.1 %

Pending CMS review.

TECFIDERA

Drugs
Dimethyl Fumarate Oral Starter Pack 120 & 240 mg
Dimethyl Fumarate Oral Capsule Delayed Release 120 mg, 240 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. 2. Complete blood cell count (CBC).

Age Restriction
18 years or older

Prescriber Restriction
Neurologist, Multiple Sclerosis Specialist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TEMAZEPAM (HRM)

Drugs
Temazepam Oral Capsule 7.5 MG, 15 MG, 22.5 MG, 30 MG

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of insomnia. 2. If member is concurrently prescribed an opioid, the prescriber must: a) provide an attestation confirming assessment of the risks associated with concurrent benzodiazepine and opioid use, and determination that the benefits outweigh the risks AND b) submit a documented plan outlining the strategy for tapering and discontinuation of one or both agents, as appropriate.

Age Restriction
Prior authorization (PA) is mandated for members aged 65 and older.

Prescriber Restriction
None

Coverage Duration
Members without concurrent opioid use: 12 months. Other: 90 days.

Other Criteria
For member with concurrent prescribed opioid, exemption will apply to individuals with a diagnosis of cancer, sickle cell disease, or those receiving hospice or palliative care services.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TEPMETKO

Drugs
Tepmetko Oral Tablet 225 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal epithelial transition (MET) exon 14 skipping alterations.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TERIPARATIDE

Drugs
Teriparatide Solution Pen-Injector 560 MCG/2.24ML Subcutaneous

Pending CMS review.

THALOMID

Drugs
Thalomid Oral Capsule 50 mg, 100 mg

Exclusion Criteria
Pregnancy

Required Medical Information
1. Diagnosis of any of the following: A) Newly diagnosed multiple myeloma (MM) in combination with dexamethasone. B) Acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). C) Maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. 2. Pregnancy test in women with reproductive potential.

Age Restriction
12 years or older

Prescriber Restriction
Hematologist, Oncologist, Infectious Disease Specialist, Dermatologist.

Coverage Duration
12 months

Other Criteria
Pregnancy test performed within 10-14 days and the second test within 24 hours prior to prescribing THALOMID therapy.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

THIOGUANINE

Drugs
Tabloid Oral Tablet 40 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TIBSOVO

Drugs
Tibsovo Oral Tablet 250 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following with a susceptible IDH1 mutation as detected by an FDA approved test: A) Newly Diagnosed Acute Myeloid Leukemia (AML), in combination with azacitidine or as monotherapy for the treatment of newly diagnosed AML in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. B) Relapsed or refractory AML, for the treatment of adult patients with relapsed or refractory AML. C) Relapsed or refractory Myelodysplastic Syndromes (MDS), for the treatment of adult patients with relapsed or refractory myelodysplastic syndromes. D)Locally Advanced or Metastatic Cholangiocarcinoma, for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma who have been previously treated.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Gastroenterologist, Hepatologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

TIRZEPATIDE (GLP-1)

Drugs
Mounjaro Subcutaneous Solution Auto-Injector 10 mg/0.5ml
Mounjaro Subcutaneous Solution Auto-Injector 12.5 mg/0.5ml
Mounjaro Subcutaneous Solution Auto-Injector 15 mg/0.5ml
Mounjaro Subcutaneous Solution Auto-Injector 2.5 mg/0.5ml
Mounjaro Subcutaneous Solution Auto-Injector 5 mg/0.5ml
Mounjaro Subcutaneous Solution Auto-Injector 7.5 mg/0.5ml

Exclusion Criteria
Personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine. Neoplasia syndrome type 2 (MEN 2).

Required Medical Information
1. Diagnosis of Type 2 diabetes mellitus for glycemic control. A1C.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TOBI PODHALER

Drugs
Tobi Podhaler Capsule 28 MG

Pending CMS review.

TOPICAL TESTOSTERONES

Drugs
Testosterone Transdermal Gel 12.5 mg/Act (1%), 25 mg/2.5gm (1%), 50 mg/5gm (1%), 20.25 mg/act (1.62%)

Exclusion Criteria
Not covered for the treatment of sexual dysfunction. Men with carcinoma of the breast or known or suspected carcinoma of the prostate.

Required Medical Information
1. Diagnosis of any of the following: A) Hypogonadotropic hypogonadism. OR B) Primary hypogonadism. 2. Low testosterone levels have been confirmed with laboratory test (total or free testosterone) according to standard male lab reference values before starting or continuing therapy.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TRAMETINIB

Drugs
Mekinist Oral Solution Reconstituted 0.05 mg/ml
Mekinist Oral Tablet 0.5 mg, 2 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TREMFYA

Drugs
Tremfya One-Press Solution Pen-Injector 100 MG/ML Subcutaneous
Tremfya Pen Solution Auto-Injector 200 MG/2ML Subcutaneous
Tremfya Subcutaneous Solution Prefilled Syringe 100 Mg/Ml, 200Mg/2Ml
Tremfya-CD/UC Induction Solution Auto-Injector 200 MG/2ML Subcutaneous

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: A) Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy, B) Active psoriatic arthritis, C) Moderate-to-severe active ulcerative colitis, OR D) Moderate-to-severe active Crohn disease. 2. Negative test results PPD for latent tuberculosis. 3. Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)].

Age Restriction
For plaque psoriasis and psoriatic arthritis: 6 years of age and older who also weigh at least 40 kg. Other: 18 years of age and older.

Prescriber Restriction
Rheumatologist, Dermatologist or Gastroenterologist.

Coverage Duration
12 months

Other Criteria
For renewal, patient has stable disease or has improved while on therapy.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TRETINOIN

Drugs
Tretinoin External Cream 0.025 %, 0.05%, 0.1%
Tretinoin External Gel 0.01 %, 0.025%

Pending CMS review.

TRIKAFTA

Drugs
Trikafta Tablet Therapy Pack 100-50-75 & 150 MG Oral
Trikafta Tablet Therapy Pack 50-25-37.5 & 75 MG Oral
Trikafta Therapy Pack 100-50-75 & 75 MG Oral
Trikafta Therapy Pack 80-40-60 & 59.5 MG Oral

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of cystic fibrosis (CF) and patient has at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on clinical and/or in vitro data. 2. FDA-cleared CF mutation test to confirm the presence of at least one indicated mutation. 3. Liver function tests: ALT, AST, alkaline, phosphatase, and bilirubin.

Age Restriction
2 years and older

Prescriber Restriction
Pneumologist, Pulmonologist or Cystic Fibrosis Specialist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TRIPTORELIN (LHRH)

Drugs
Trelstar Mixject Suspension Reconstituted 3.75 mg, 11.25 mg, 22.5 mg

Pending CMS review.

TRUQAP

Drugs
Truqap Oral Tablet 200 Mg
Truqap Tablet Therapy Pack 160 MG Oral

Pending CMS review.

TUKYSA

Drugs
Tukysa Oral Tablet 50 mg, 150 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) Advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases: in combination with trastuzumab and capecitabine for treatment of adult patients who have received one or more prior anti-HER2-based regimens in the metastatic setting. B) Colorectal Cancer: in combination with trastuzumab for the treatment of adult patients with RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Gastroenterologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

TURALIO

Drugs
Turalio Oral Capsule 125 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery. 2.Liver function test (AST,ALT, ALP bilirubin) and serum creatinine.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TYENNE

Drugs
Tyenne Solution Auto-Injector 162 MG/0.9ML Subcutaneous
Tyenne Solution Prefilled Syringe 162 MG/0.9ML Subcutaneous

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of one of the following: a) moderately to severely active Rheumatoid Arthritis (RA) in patients who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs), b) Giant Cell Arteritis (GCA), c) Polyarticular Juvenile Idiopathic Arthritis (PJIA) or d) Systemic Juvenile Idiopathic Arthritis (SJIA).

Age Restriction
For (RA) and (GCA): 18 years or older. For (PJIA) and (SJIA): 2 years of age and older.

Prescriber Restriction
Rheumatologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

TYGACIL

Drugs
Tigecycline Intravenous Solution Reconstituted 50 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of complicated skin and skin structure infections, complicated intra-abdominal infection or community acquired bacterial pneumonia.

Age Restriction
18 years or older

Prescriber Restriction
Infections Disease Specialist, Dermatologist, Pneumologist, Gastroenterologist

Coverage Duration
14 days

Other Criteria
Subject to B vs D review.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

TYKERB

Drugs
Lapatinib Ditosylate Oral Tablet 250 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A)Treatment in combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress human epidermal growth factor receptor 2 (HER2) and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. OR B) In combination with letrozole for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated. 2. LVEF.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months.

Other Criteria
1. For breast cancer, new patient must have HER2-positive breast cancer for approval of lapatinib. 2. Normal LVEF is required before starting therapy.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

TYMLOS

Drugs
Tymlos Subcutaneous Solution Pen-Injector 3120 Mcg/1.56ml

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) For the treament of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. B) For the treatment to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. 2. Patient has tried and failed two oral biphosphonates. 3. Bone mineral density (BMD) T-score.

Age Restriction
18 years or older

Prescriber Restriction
Endocrinologists, Rheumatologists, Orthopedists, Gynecologist

Coverage Duration
24 months (max. length of therapy per lifetime)

Other Criteria
Tymlos will be approved for the covered osteoporosis indications if the patient has trial and failure, contraindication, or intolerance to two oral bisphosphonates (eg., alendronate, ibandronate). Prior History of medication in claims, MD shall provide documentation of medical record or pharmacy claims processing thru another benefit to comply with previous utilization. OR if the patient has severe renal impairment (eg, creatinine clearance less than 30 mL/min) or chronic kidney disease, or if the patient has multiple vertebral fractures in the setting of vertebral T-scores less than -2.5. Treatment duration of parathyroid hormones (e.g., Forteo [teriparatide], Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patients lifetime.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

TYVASO

Drugs
Tyvaso DPI Maintenance Kit Powder 16 MCG Inhalation
Tyvaso DPI Maintenance Kit Powder 32 MCG Inhalation
Tyvaso DPI Maintenance Kit Powder 48 MCG Inhalation
Tyvaso DPI Maintenance Kit Powder 64 MCG Inhalation
Tyvaso DPI Maintenance Kit Powder 80 MCG Inhalation
Tyvaso DPI Titration Kit Powder 16 & 32 & 48 MCG Inhalation
Tyvaso DPI Maintenance Kit Powder 112 x 32MCG & 112 x64MCG Inhalation
Tyvaso DPI Maintenance Kit Powder 112 x 48MCG & 112 x64MCG Inhalation
Tyvaso DPI Maintenance Kit Powder 112 x 48MCG & 112 x80MCG Inhalation

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) Pulmonary arterial hypertension (PAH, WHO Group 1) to improve exercise ability and diagnosis confirmed by right heart catheterization required. B) Pulmonary hypertension associated with interstitial lung disease (PH-ILD,WHO Group 3) to improve exercise ability. Right heart catheterization is not required for PH-ILD diagnosis.

Age Restriction
None

Prescriber Restriction
Pneumologist, Pulmonologist, Cardiologist.

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

UPTRAVI

Drugs
Uptravi Oral Tablet Titration Therapy Pack 200 & 800 MCG
Uptravi Oral Tablet 200 MCG, 400 MCG, 600 MCG, 800 MCG, 1000 MCG, 1200 MCG, 1400 MCG, 1600 MCG

Pending CMS review.

USTEKINUMAB

Drugs
Selarsdi Solution 45 MG/0.5ML Subcutaneous
Selarsdi Solution Prefilled Syringe 45 MG/0.5ML Subcutaneous
Selarsdi Solution Prefilled Syringe 90 MG/ML Subcutaneous

Pending CMS review.

VALCHLOR

Drugs
Valchlor External Gel 0.016 %

Exclusion Criteria
None

Required Medical Information
Diagnosis of Stage 1A or 1B mycosis fungoides-type cutaneous t-cell lymphoma in patients who have received prior skin-directed therapy.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Dermatologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

VALTOCO

Drugs
Valtoco 10 Mg Dose Nasal Liquid 10 mg/0.1ml
Valtoco 15 Mg Dose Nasal Liquid Therapy Pack 7.5 mg/0.1ml
Valtoco 20 Mg Dose Nasal Liquid Therapy Pack 10 mg/0.1ml
Valtoco 5 Mg Dose Nasal Liquid 5 mg/0.1ml

Exclusion Criteria
Acute narrow-angle glaucoma. Hypersensitivity to diazepam.

Required Medical Information
Diagnosis of epilepsy with intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patients usual seizure pattern.

Age Restriction
2 years or older

Prescriber Restriction
Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

VANFLYTA

Drugs
Vanflyta Oral Tablet 17.7 MG, 26.5 MG

Exclusion Criteria
Patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, history of ventricular arrhythmias or history of torsade de pointes.

Required Medical Information
1. Diagnosis of acute myeloid leukemia (AML, newly diagnosed) with FLT3 internal tandem duplication (ITD)-positive mutation in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy. 2. FLT3 internal tandem duplication (ITD)-positive mutation confirmed by an FDA-approved test.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

VELSIPITY

Drugs
Velsipity Tablet 2 MG Oral

Exclusion Criteria
1. In the last 6 months, experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure. 2. History or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker.

Required Medical Information
1. Diagnosis of moderately to severely active ulcerative colitis. 2. Complete blood count (CBC). 3. Transaminase and bilirubin levels. 4. Baseline fundus evaluation.

Age Restriction
18 years of age and older

Prescriber Restriction
Gastroenterologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) The member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

VEMLIDY

Drugs
Vemlidy Oral Tablet 25 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of chronic hepatitis B virus infection with compensated liver disease. 2. HIV test.

Age Restriction
6 years or older

Prescriber Restriction
Gastroenterologist, Hepatologist, Infectious Disease Specialist

Coverage Duration
12 months

Other Criteria
For patients HIV positive, drug should not be use as monotherapy.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

VENCLEXTA

Drugs
Venclexta Starting Pack Oral Tablet 10 & 50 & 100 mg
Venclexta Oral Tablet 10 mg, 50 mg, 100 mg

Exclusion Criteria
Concomitant use of strong CYP3A inhibitors at initiation and during ramp-up phase in CLL or SLL is contraindicated.

Required Medical Information
1. Indications of any of the following: A) Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), OR B) In combination with azacitidine or decitabine or low-dose cytarabine for the treatment of 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. 2. Assessment of risk for Tumor Lysis Syndrome.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

VEOZAH

Drugs
Veozah Oral Tablet 45 Mg

Exclusion Criteria
Known cirrhosis. Severe renal impairment or end-stage renal disease. Concomitant use with CYP1A2 inhibitors.

Required Medical Information
1. Diagnosis of moderate to severe vasomotor symptoms due to menopause. 2. Try and failure (at least for 30 days) or contraindication or intolerance to one of the following: a) Hormonal therapy (e.g., estradiol), b) Non-hormonal therapy [e.g., clonidine, gabapentin, selective serotonin inhibitors (e.g., paroxetine), serotonin and norepinephrine reuptake inhibitors (e.g., venlafaxine).

Age Restriction
18 years of age or older

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
For re authorization, documentation of positive clinical response to therapy defined by example as a decrease in frequency and severity of vasomotor symptoms from baseline.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

VERQUVO

Drugs
Verquvo Oral Tablet 2.5 mg, 5 mg, 10 mg

Pending CMS review.

VERZENIO

Drugs
Verzenio Oral Tablet 50 mg, 100 mg, 150 mg, 200 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: A) In combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence. B) In combination with an aromatase inhibitor as initial endocrine based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. C) In combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. D) 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
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

VIGAFYDE

Drugs
Vigafyde Oral Solution 100 mg/ml

Exclusion Criteria
None

Required Medical Information
Diagnosis infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

Age Restriction
1 month of age or older.

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

VIJOICE

Drugs
Vijoice Packet 50 MG Oral
Vijoice Tablet Therapy Pack 125 MG Oral
Vijoice Tablet Therapy Pack 200 & 50 MG Oral
Vijoice Tablet Therapy Pack 50 MG Oral

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of severe manifestations of PIK3CA Related Overgrowth Spectrum (PROS) who require systemic therapy. 2. Member has a PIK3CA mutation as confirmed by genetic testing.

Age Restriction
2 years or older

Prescriber Restriction
Prescribed by or in consultation with a physician that specializes in treatment of genetic disorders.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

VITRAKVI

Drugs
Vitrakvi Oral Solution 20 mg/ml
Vitrakvi Oral Capsule 25 mg, 100 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of solid tumors AND, have a neurotrophic receptor tyrosine 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 no satisfactory alternative treatments or that have progressed following treatment. 1. Baseline liver function test (ALT, AST, ALP, and bilirubin).

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

VONJO

Drugs
Vonjo Oral Capsule 100 mg

Exclusion Criteria
Concomitant use of strong CYP3A4 inhibitors or inducers.

Required Medical Information
1.Diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 X 10 ^9/L. 2. Platelet count.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

VOQUENZA DUAL PAK

Drugs
Voquezna Dual Pak Therapy Pack 500-20 MG Oral

Pending CMS review.

VOQUENZA TRIPLE PAK

Drugs
Voquezna Triple Pak Therapy Pack 500-500-20 MG Oral

Pending CMS review.

VORANIGO

Drugs
Voranigo Oral Tablet 10 mg, 40 mg

Exclusion Criteria
None

Required Medical Information
1) Diagnosis of Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection. 2) Negative pregnancy test for woman in reproductive age.

Age Restriction
12 years or older

Prescriber Restriction
Neurosurgeons, Neurologists, Neuro-oncologists, Hematologist, Oncologist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

VORICONAZOLE

Drugs
Voriconazole Intravenous Solution Reconstituted 200 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis. 2. Route of administration is intravenous.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
6 months

Other Criteria
Subject to B vs D review.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

Drugs
Vosevi Oral Tablet 400-100-100 mg

Pending CMS review.

VOTRIENT

Drugs
Pazopanib Hcl Oral Tablet 200 Mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) Advanced renal cell carcinoma. B) Advanced soft tissue sarcoma (STS) who have received prior chemotherapy. 2. Serum transaminase levels and bilirubin before initiating treatment.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

VOWST

Drugs
Vowst Oral Capsule

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of recurrent Clostridioides difficile infection (rCDI) as defined by the presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days and positive stool test for Clostridioides difficile toxin. 2. Member has had one or more recurrence(s) of CDI following an initial episode of CDI. 3. Member has completed at least 10 days of antibiotic therapy for rCDI 2 with oral vancomycin or Dificid (fidaxomicin), 2 to 4 days prior to initiating Vowst.

Age Restriction
18 years of age or older

Prescriber Restriction
Gastroenterologist, Infectious disease specialist.

Coverage Duration
1 month

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

VUMERITY

Drugs
Vumerity Oral Capsule Delayed Release 231 mg

Exclusion Criteria
Co-administration with dimethyl fumarate.

Required Medical Information
1.Diagnosis of relapsing forms of multiple sclerosis (MS) including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. 2. Complete blood count. 3. Liver function test (ALT, AST, ALP and total bilirubin).

Age Restriction
18 years or older

Prescriber Restriction
Neurologist or MS Specialist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

VYNDAMAX, VYNDAQEL

Drugs
Vyndamax Oral Capsule 61 MG

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis to reduce cardiovascular mortality and cardiovascular-related hospitalization. 2. Member present symptoms of cardiomyopathy and heart failure (e.g., orthostatic hypotension, peripheral edema, dyspnea). 3. Diagnosis confirmed by pathogenic TTR mutation (e.g., V30M) OR cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits OR all of the following: Echocardiagram or cardiac magnetic resonance imaging suggestive of amyloidosis AND radionuclide imaging showing grade 2 or 3 cardiac uptake AND Absence of light chain amyloidosis.

Age Restriction
18 years or older

Prescriber Restriction
Cardiologist

Coverage Duration
12 months

Other Criteria
For continuation, member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

Drugs
Vyvgart Hytrulo Subcutaneous Solution Prefilled Syringe 1000-10000 MG-UNT/5ML

Pending CMS review.

WELIREG

Drugs
Welireg Oral Tablet 40 mg

Pending CMS review.

Drugs
Winrevair Kit 2 x 45 MG Subcutaneous
Winrevair Kit 2 x 60 MG Subcutaneous
Winrevair Kit 45 MG Subcutaneous
Winrevair Kit 60 MG Subcutaneous

Pending CMS review.

XALKORI

Drugs
Xalkori Oral Capsule 200 mg, 250 mg
Xalkori Oral Capsule Sprinkle 20 mg, 50 mg, 150 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following, as detected by an FDA-approved test: A) Metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positiv. B) Relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. C) Unresectable, recurrent or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive.

Age Restriction
None

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

XCOPRI

Drugs
Xcopri (250 MG Daily Dose) Tablet Therapy Pack 100 & 150 MG Oral
Xcopri (350 MG Daily Dose) Tablet Therapy Pack 150 & 200 MG Oral
Xcopri Tablet 100 MG Oral
Xcopri Tablet 150 MG Oral
Xcopri Tablet 200 MG Oral
Xcopri Tablet 25 MG Oral
Xcopri Tablet 50 MG Oral
Xcopri Tablet Therapy Pack 14 x 12.5 MG & 14 x 25 MG Oral
Xcopri Tablet Therapy Pack 14 x 150 MG & 14 x200 MG Oral
Xcopri Tablet Therapy Pack 14 x 50 MG & 14 x100 MG Oral

Exclusion Criteria
Familial Short QT syndrome.

Required Medical Information
Diagnosis of partial-onset seizures.

Age Restriction
18 years or older

Prescriber Restriction
Neurologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

XDEMVY

Drugs
Xdemvy Ophthalmic Solution 0.25 %

Exclusion Criteria
None

Required Medical Information
Diagnosis of Demodex blepharitis

Age Restriction
18 years of age and older

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
For renewal, patient has stable disease or has improved while on therapy.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

Drugs
Tofacitinib Citrate Oral Tablet 5 mg, 10 mg
Tofacitinib Citrate ER Oral Tablet Extended Release 24 Hour 11 mg, 22 mg
Tofacitinib Citrate Oral Solution 1 mg/ml

Pending CMS review.

Drugs
Tetrabenazine Oral Tablet 12.5 mg, 25 mg

Pending CMS review.

XERMELO

Drugs
Xermelo Oral Tablet 250 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy, inadequately controlled by SSA therapy.

Age Restriction
18 years or older

Prescriber Restriction
Oncologist, Endocrinologist

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

Drugs
Bilprevda Subcutaneous Solution 120 Mg/1.7ml

Exclusion Criteria
Hypocalcemia, as defined by the reporting lab.

Required Medical Information
For the treatment of any of the following: 1. Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors OR 2. Adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity OR 3. Hypercalcemia of malignancy refractory to bisphosphonate therapy.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
Subject to B vs D review. For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

XIFAXAN

Drugs
Xifaxan Oral Tablet 200 mg, 550 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis or intended use for one of the following, a. travelers diarrhea (TD) caused by noninvasive strains of Escherichia coli. b. Reduction in risk of overt hepatic encephalopathy (HE). c. Treatment of irritable bowel syndrome with diarrhea (IBS-D).

Age Restriction
For Traveler's diarrhea, 12 years or older. For the other indications, 18 years or older.

Prescriber Restriction
Gastroenterologist, Hepatologist or Infectious Disease Specialist.

Coverage Duration
Authorization will be for 12 months. Approval for Travelers Diarrhea will be as requested

Other Criteria
For hepatic encephalopathy, prior trial of lactulose. Prior History of medication in claims, MD shall provide documentation of medical record or pharmacy claims processing thru another benefit to comply with previous utilization.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

XOLAIR

Drugs
Xolair Subcutaneous Solution Prefilled Syringe 150 mg/ml, 75 mg/0.5ml, 300mg/2ml
Xolair Subcutaneous Solution Reconstituted 150 mg
Xolair Subcutaneous Solution Auto-Injector 75mg/0.5ml, 150mg/ml, 300mg/2ml

Pending CMS review.

XOLREMDI

Drugs
Xolremdi Oral Capsule 100 mg

Pending CMS review.

XOSPATA

Drugs
Xospata Oral Tablet 40 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of acute myeloid leukemia (AML), relapsed or refractory with a FLT3 mutation as detected by an FDA-approved test.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

XPOVIO

Drugs
Xpovio (100 MG Once Weekly) Tablet Therapy Pack 50 MG Oral
Xpovio (40 MG Once Weekly) Tablet Therapy Pack 10 MG Oral
Xpovio (40 MG Once Weekly) Tablet Therapy Pack 40 MG Oral
Xpovio (40 MG Twice Weekly) Tablet Therapy Pack 40 MG Oral
Xpovio (60 MG Once Weekly) Tablet Therapy Pack 60 MG Oral
Xpovio (60 MG Twice Weekly) Tablet Therapy Pack 20 MG Oral
Xpovio (80 MG Once Weekly) Tablet Therapy Pack 40 MG Oral
Xpovio (80 MG Twice Weekly) Tablet Therapy Pack 20 MG Oral
Xpovio (80 MG Once Weekly) Tablet Therapy Pack 80 MG Oral

Pending CMS review.

XTANDI

Drugs
Xtandi Oral Capsule 40 mg
Xtandi Oral Tablet 40 mg, 80 mg

Pending CMS review.

XYREM

Drugs
Sodium Oxybate Oral Solution 500 mg/ml

Exclusion Criteria
Concomitant treatment with sedative hypnotic agents. Succinic semialdehyde dehydrogenase deficiency.

Required Medical Information
Diagnosis of one of the following: A) narcolepsy with excessive daytime sleepiness, cataplexy or both confirmed by sleep lab evaluation (e.g., multiple sleep latency test, polysomnography) and for patients with excessive daytime sleepiness, patient has had a previous trial with or has a contraindication, intolerance, or allergy to modafinil, armodafinil, methylphenidate, dextroamphetamine, or mixed amphetamine salts B) fibromyalgia syndrome and patient had a previous trial (of at least 30 days) with, or has a contraindication, intolerance, or allergy to two of the following: duloxetine, milnacipran, or pregabalin.

Age Restriction
None

Prescriber Restriction
None

Coverage Duration
Initial: 6 months. Renewal: 12 months.

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, Some Medically-accepted Indications.

Off Label Uses
Fibromyalgia

Part B Prerequisite
No

Prerequisite Therapy Required
Yes

ZAVESCA

Drugs
Miglustat Oral Capsule 100 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of Type 1 Gaucher Disease to be used as monotherapy in patients whom enzyme replacement therapy (e.g. cerezyme) is not a therapeutic option.

Age Restriction
18 years or older

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
For continuation based on both of the following criteria: (1) The member continues to derive clinical benefit from therapy, which may include slowing of disease progression, symptom control, preservation of function, or other clinically appropriate outcomes and (2) Member has not experienced any serious adverse events while on the medication.

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

ZEJULA

Drugs
Zejula Oral Tablet 100 mg, 200mg, 300mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following: A) For the maintenance treatment of adult patient with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy. OR B) For the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

ZELBORAF

Drugs
Zelboraf Oral Tablet 240 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of any of the following: A) Unresectable or metastatic melanoma with BRAF V600E mutation. B) Erdheim-Chester Disease with BRAF V600 mutation. 2. Baseline: electrocardiogram, electrolytes, liver enzymes, and bilirubin. 3. Mutation detected by an FDA-approved test.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Dermatologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ZENBEXUS

Drugs
Zenbexs Oral Caspule 0.75 mg, 1 mg

Pending CMS review.

ZOLINZA

Drugs
Zolinza Oral Capsule 100 mg

Exclusion Criteria
None

Required Medical Information
1.Diagnosis of cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies. 2. Pregnancy test in females with reproductive potential prior to initiation of therapy.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

ZOLPIDEM (HRM)

Drugs
Zolpidem Tartrate ER Tablet Extended Release 12.5 MG Oral
Zolpidem Tartrate Tablet 10 MG Oral

Exclusion Criteria
None

Required Medical Information
Provider attestation is required confirming that the requested medication is classified as a high-risk medication (HRM) in the elderly, and that the anticipated clinical benefits outweigh the potential risks; and the member has previously tried and failed, or was unable to tolerate, at least one non–high-risk therapeutic alternative, including ramelteon, doxepin 3 mg tablet or doxepin 6 mg tablet.

Age Restriction
Prior authorization (PA) is mandated for members aged 65 and older.

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

ZTALMY

Drugs
Ztalmy Oral Suspension 50 mg/ml

Exclusion Criteria
None

Required Medical Information
Diagnosis of seizures associated with cyclin -dependent kinase-like 5 (CDKL5) deficiency disorder (CDD).

Age Restriction
2 years or older

Prescriber Restriction
Neurologist, Geneticist.

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ZURZUVAE

Drugs
Zurzuvae Oral Capsule 20 Mg, 25 Mg, 30Mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of postpartum depression.

Age Restriction
18 years or older

Prescriber Restriction
None

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ZYKADIA

Drugs
Zykadia Oral Tablet 150 mg

Exclusion Criteria
None

Required Medical Information
1. Diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive. 2. Confirmation of ALK-positive mutation as detected by an FDA-approved test.

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

No

ZYTIGA

Drugs
Abiraterone Acetate Oral Tablet 250 mg, 500 mg

Exclusion Criteria
None

Required Medical Information
Diagnosis of any of the following in combination with prednisone: A) Metastatic castration-resistant prostate cancer (CRPC). B) Metastatic high-risk castration-sensitive prostate cancer (CSPC).

Age Restriction
18 years or older

Prescriber Restriction
Hematologist, Oncologist, Urologist

Coverage Duration
12 months

Other Criteria
None

Indications
All FDA-approved Indications.

Off Label Uses
None

Part B Prerequisite
None

Prerequisite Therapy Required

Yes

Index

A

Abiraterone Acetate Oral Tablet 318
Acetylcysteine Solution..... 39
acitretin..... 2
ACTHAR 3
ACTHAR GEL SUBCUTANEOUS PEN-INJECTOR..... 3
ACTIMMUNE 4
Acyclovir Sodium Solution.... 39
Adapalene Cream 6
Adapalene Gel..... 6
adefovir dipivoxil 105
ADEMPAS..... 8
AIMOVIG SUBCUTANEOUS SOLUTION AUTO-INJECTOR 140 MG/ML, 70 MG/ML 11
Akeega..... 12
ALECENSA..... 13
alosetron hcl 152
Alprazolam Oral Tablet..... 14
Alunbrig Oral Tablet 15
Alunbrig Oral Tablet Therapy Pack 15
Alyq..... 7
Ambrisentan 143
Amphotericin B Liposome Suspension Reconstituted... 39
Amphotericin B Solution Reconstituted..... 39
Ampicillin Sodium Solution Reconstituted..... 39
Aprepitant Capsule Therapy Pack 39
Aprepitant Oral..... 39
ARCALYST..... 18
ARIKAYCE 19
armodafinil 174
atovaquone oral 160
Augtyro..... 21
AUSTEDO 22
AUSTEDO XR..... 22
Avmapki..... 23
Avonex 24
AYVAKIT..... 26
Azathioprine Oral Tablet..... 39

B

BAFIERTAM..... 28
BALVERSA..... 29
BAXDELA..... 31
Benlysta..... 32
BESREMI..... 33
BETASERON 123
Bexarotene External Gel 240
Bexarotene oral capsule..... 240
Bildyos..... 197
Bilprevda 301
Bivigam Solution..... 39
Bosulif..... 35
Brivaracetam 36
BRUKINSA..... 37
Budesonide Suspension..... 39

C

CABOMETYX..... 43
Calquence 45
CAMZYOS 46
Carglumic 47
Caspofungin Acetate Solution Reconstituted..... 39
CAYSTON 48
Cefoxitin Sodium 39
Cefuroxime Sodium Solution. 39
CHOLBAM..... 49
Clinimix/Dextrose 39
Clonazepam..... 50
Clorazepate Dipotassium..... 51
Colistimethate Sodium (Cba) . 39
Cometriq..... 44
COPIKTRA..... 52
Cortrophin 54
Cosentyx..... 55
COTELLIC..... 56
CRESEMBA 57
Cromolyn Sodium 39
Cyanocobalamin Solution 39
Cyclobenzaprine..... 58
Cyclophosphamide Oral..... 39
Cyclosporine Modified..... 39
Cyclosporine Modified Oral Solution 39
Cyclosporine Oral..... 39

D

Dalfampridine ER..... 16
DANZITEN..... 60
Dasatinib..... 230
Daurismo Oral Tablet 100 Mg, 25 Mg..... 61
DAYBUE 62
Deferasirox 86
deferiprone..... 88
Diacomit 63
Diazepam Intensol Concentrate 64
Diazepam Oral Tablet..... 64
Diazepam Solution 64
dimethyl fumarate..... 245
Drizalma Sprinkle..... 67
Dronabinol Oral..... 39
Droxidopa 169
Duloxetine Hcl Oral Capsule.. 67
Dupixent 69

E

Eligard 145
Eltrombopag Olamine 198
Emend Oral Suspension 40
EMGALITY 70
ENBREL Mini..... 71
ENBREL Subcutaneous Solution..... 71
ENBREL SureClick..... 71
Engerix-B Suspension 40
Ensacove..... 74
Entyvio 75
Envarsus XR..... 40
EPIDIOLEX 77
Erivedge..... 78
ERLEADA 79
erlotinib hcl..... 239
Eslicarbazepine..... 17
Estazolam Oral Tablet 82
EUCRISA..... 83
Eulexin..... 84
Everolimus Oral Tablet 10, 40
Everolimus Oral Tablet 0.25 Mg 0.5 Mg 0.75 Mg..... 40
EVRYSDI..... 85

F

FASENRA..... 87
FERRIPROX ORAL SOLUTION..... 88
FILSPARI..... 90
Fingolimod 99

Fintepla....91
Firmagon....93
Fluconazole In Sodium Chloride Solution....40
FOTIVDA....94
Fruzaqla....95
G
Gamunex-C Solution....40
GATTEX....97
GAVRETO....98
Gefitinib....124
Gengraf Oral Capsule....40
Gilotrif....9
Glatiramer Acetate Subcutaneous Solution Prefilled Syringe 40 Mg/Ml....100
Glycerol Oral Phenylbutyrate Liquid....206
Granisetron Hcl Oral....40
H
Hadlima....65
Heplisav-B Solution....40
Hernexeos....106
Hyftor....108
Hyrnuo....109
I
IBRANCE....110
Ibtrozi....111
Icatibant Acetate Subcutaneous Solution....92
ICLUSIG....112
IDHIFA....113
imatinib mesylate....114
Imbruvica....115
Imbruvica Oral Suspension....115
IMKELDI....116
INBRIJA....117
INCRELEX....118
Infed....40
Inluriyo Oral Tablet....120
Inlyta....25
Inqovi Oral Tablet....121
INREBIC....122
Intralipid Emulsion....40
Ipratropium Bromide Solution40
Ipratropium-Albuterol Solution....40
ITOVEBI....125
Ivabradine....53
Iwilfin....126
J
Jakafi....127
Jakafi XR....127
JAYPIRCA....128
JIDEYTRO....129
JOENJA....130
Juxtapid Oral Capsule....131
Jylamvo....40
Jynneos -....40
K
Kalydeco....133
KESIMPTA....134
Kisqali....135
KOMZIFTI....136
Koselugo Oral Capsule....138
Koselugo Oral Capsule Sprinkle....138
Krazati....5
L
lapatinib ditosylate....265
LAZCLUZE....140
Ledipasvir-Sofosbuvir....104
Lenvima....141
Leqembi....142
Leukine....144
Leuprolide Acetate....145
Levalbuterol Hcl Nebulization40
L-Glutamine....73
Lifyorli (125 MG DOSE....146
Lifyorli (150 MG DOSE....146
Linezolid Intravenous....147
Linezolid Oral Suspension....147
Linezolid Oral Tablet....147
Liraglutide Solution....148
LIVTENCITY....149
Lomustine Oral Capsule 10 Mg, 100 Mg, 40 Mg....101
Lorazepam Intensol Concentrate....150
Lorazepam Oral Tablet....150
Lorbrena....151
LUMAKRAS....153
Lumryz....154
Lumryz Starter Pack....154
Lupron Depot....145
LYNPARZA....155
LYTGOBI....156
M
Macitentan....181
MAVYRET....157
MAYZENT....158
MEGESTROL Oral Suspension....159
Mekinist....255
MEKTOVI....34
Methotrexate Sodium (Pf) Solution....40
Methotrexate Sodium Oral Tablet....40
Methotrexate Sodium Solution....40
Mifepristone....137
miglustat....309
Modafinil....162
Modeyso....163
MOUNJARO Subcutaneous Solution....252
Mycophenolate Mofetil Oral Capsule....40
Mycophenolate Mofetil Oral Suspension Reconstituted....40
Mycophenolate Sodium Oral Tablet Delayed Release....40
N
Nafcillin Sodium Solution Reconstituted....40
NAYZILAM....164
Neoral Oral Capsule....40
Neoral Oral Solution....40
NERLYNX....165
Nilotinib....242
NINLARO....167
Nintedanib Esylate....177
Nitisinone....168
Nityr....168
Nivestym....89
Norditropin Flexpro....103
NUBEQA....170
NUCALA....171
NUEDEXTA....172
NUPLAZID....173
Nutrilipid Emulsion....40
NUZYRA....175
O
Octagam Solution....40
Octreotide Acetate Solution....40
ODOMZO....176
Ofev....177
OGSIVEO....178

Ojemda Oral Suspension 179
Ojemda Oral Tablet 179
OJJAARA 180
Ondansetron Hcl Oral 41
Ondansetron Oral Tablet Dispersible 41
Onureg 27
OPSYNVI 182
Orfadin 168
Orgovyx 209
Orkambi 183
ORLADEYO 184
ORSERDU 185
OTEZLA 186
OTEZLA Oral Tablet Therapy Pack 186
OTEZLA XR Oral Tablet 186
Otezla/Otezla XR Initiation Pk 186
OZEMPIC Oral Tablet 224
OZEMPIC Subcutaneous Solution Pen 224
P
PANRETIN 188
pazopanib hcl 288
PEGASYS 189
Pemazyre 190
Pentamidine Isethionate Inhalation Solution Reconstituted 41
Pentamidine Isethionate Injection Solution Reconstituted 41
Perampanel Oral Suspension 96
Perampanel Oral Tablet 96
PHEBURANE 191
PIQRAY 193
Pirfenidone 81
Polymyxin B Sulfate Solution Reconstituted 41
Pomalyst 194
Premasol Solution Intravenous 41
Pretomanid 195
PREVYMIS 196
Prograf Oral Packet 41
Prolastin-C 187
Prosol Solution 41
Pulmozyme Solution 41
Pylera 199
pyrimethamine 200
PYRUKYND 201
Pyrukynd Taper Pack 201
PYRUKYND TAPER PACK ORAL TABLET THERAPY PACK 201
Q
QINLOCK 202
QULIPTA 203
R
RADICAVA 204
RALDESY 205
Recombivax Hb Suspension 41
Recorlev 207
RECORLEV 207
Relistor 161
Retacrit 80
RETEVMO 210
REVCOVI 211
REVUFORJ 212
Rezdiffra 213
REZLIDHIA 214
REZUROCK 215
riluzole 216
RINVOQ 217
ROMVIMZA 218
ROZLYTREK 219
ROZLYTREK ORAL PACKET 219
RUBRACA 220
Rufinamide 30
RYDAPT 221
S
SAJAZIR SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 92
sapropterin 139
SCEMBLIX 223
SIGNIFOR 225
sildenafil citrate oral suspension 192
sildenafil citrate oral tablet 192
Simlandi 65
Sirolimus Oral Solution 41
Sirolimus Oral Tablet 41
SIRTURO 226
SKYCLARYS 227
SKYRIZI 228
sodium oxybate 308
sodium phenylbutyrate oral powder 38
sodium phenylbutyrate oral tablet 38
Sofosbuvir-Velpatasvir 76
Soltamox 238
SOMAVERT 229
Sorafenib Tosylate 166
Stivarga 208
sunitinib malate 231
SYNAREL 232
T
Tabloid 250
TABRECTA 233
Tacrolimus ER Oral Capsule 41
Tacrolimus Oral Capsule 41
tadalafil 234
Tadalafil 7
TAFINLAR 59
TAGRISSO 235
TAKHZYRO SUBCUTANEOUS SOLUTION 236
TALZENNA 237
Tarpeyo 241
tasimelteon 107
TAVNEOS 243
Tazarotene External Cream 244
Tazarotene External Gel 244
temazepam 246
Tenivac Injectable 41
TEPMETKO 247
Teriflunomide 20
teriparatide 248
testosterone transdermal gel 254
tetrabenazine 299
THALOMID 249
TIBSOVO 251
tigecycline 264
Tobi 253
Tobramycin Nebulization Solution 41
Tobramycin Sulfate Solution 41
Tofacitinib Citrate ER 298
Tofacitinib Citrate Oral Solution 298
Tofacitinib Citrate Oral Tablet 298
Tolvaptan 132

Tpn Electrolytes Solution Intravenous 41
Travasol Solution 41
Trelstar Mixject 259
TREMFYA 256
tretinoin external cream 257
tretinoin external gel 257
TRIKAFTA ORAL 258
Trophamine Solution 41
TRULICITY Subcutaneous Solution 68
Truqap 260
TUKYSA 261
TURALIO 262
TYENNE SUBCUTANEOUS 263
TYMLOS 266
TYVASO 267
U
Uptravi 268
V
VALCHLOR 270
VALTOCO 10 MG DOSE ... 271
VALTOCO 15 MG DOSE ... 271
VALTOCO 20 MG DOSE ... 271
VALTOCO 5 MG DOSE 271
VANFLYTA 272
Velsipity 273
VEMLIDY 274
VENCLEXTA 275
VENCLEXTA STARTING PACK 275
VEOZAH 276
VERQUVO 277
VERZENIO 278
Vigabatrin Oral Packet 222
Vigabatrin Oral Tablet 222
VIGAFYDE 279
Vijoice 280
VITRAKVI oral capsule 281
VITRAKVI oral solution 281
VONJO 282
Voquezna Dual Pak 283
Voquezna Triple Pak 284
VORANIGO 285
voriconazole intravenous 286
VOSEVI 287
VOWST 289
VUMERITY 290
Vyndamax 291
VYVGART 292
W
WEGOVY Oral Tablet 224
Wegovy Subcutaneous Solution 224
WELIREG 293
WINREVAIR 294
X
XALKORI ORAL CAPSULE 295
XALKORI ORAL CAPSULE SPRINKLE 295
Xatmep Solution 41
XCOPRI 296
XDEMVY 297
XERMELO 300
XIFAXAN 302
XOLAIR 303
XOLREMDI 304
XOSPATA 305
XPOVIO 306
XTANDI ORAL CAPSULE 307
XTANDI ORAL TABLET ... 307
Z
ZARXIO 89
ZEJULA ORAL CAPSULE . 310
ZEJULA ORAL TABLET ... 310
ZELBORAF 311
ZENBEXUS 312
ZOLINZA 313
Zolpidem 314
ZTALMY 315
ZURZUVAE ORAL CAPSULE 316
ZYKADIA ORAL TABLET 317
Zymfentra 119