2023 Prior Authorization Criteria

ABIRATERONE

Affected Drugs

ABIRATERONE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Severe hepatic impairment (Child-Pugh Class C). NYHA Class III or IV heart failure. LVEF is less than 50%.

Required Medical Information

Abiraterone is administered in combination with Prednisone. AST and ALT less than or equal to 2.5X ULN and total bilirubin less than or equal to 1.5X ULN. Serum potassium is within normal limits prior to initiation of abiraterone.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Urologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ACITRETIN

Affected Drugs

ACITRETIN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Females who are pregnant, or who intend to become pregnant during acitretin therapy or at any time for at least 3 years following discontinuation of acitretin therapy. Females who may not use reliable contraception while undergoing treatment with acitretin and for at least 3 years following discontinuation of treatment with acitretin. Patients with severely impaired liver or kidney function. Patients with chronic abnormally elevated blood lipid values. The combined use of acitretin and methotrexate. The combined use of acitretin and tetracyclines.

Required Medical Information

Females of reproductive potential must have had 2 negative urine or serum pregnancy tests with a sensitivity of at least 25 mIU/mL before receiving the initial acitretin prescription. Lipid Panel, Liver function tests: ALT, AST, LDH.

Age Restrictions

N/A

Prescriber Restrictions

Dermatologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The documented use of at least one formulary topical corticosteroid (e.g., clobetasol propionate, fluocinonide, etc.) for the current condition is required prior to the initiation of acitretin.

ACTIMMUNE

Affected Drugs

ACTIMMUNE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

In patients with chronic granulomatous disease (CGD), the member will be using Actimmune to reduce the frequency and severity of serious infections. In patients with severe malignant osteopetrosis (SMO), the member will be using Actimmune to delay time to disease progression.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ADEMPAS

Affected Drugs

ADEMPAS®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential. The concurrent use of nitrates or nitric oxide donors (e.g., nitroglycerin, isosorbide mononitrate or dinitrate, amyl nitrite, etc.) or specific PDE-5 inhibitors (e.g., sildenafil, tadalafil, etc.) or nonspecific PDE inhibitors (e.g., dipyridamole, theophylline, etc.).

Required Medical Information

A diagnosis of 1) pulmonary arterial hypertension (PAH) (WHO Group 1) or 2) persistent or recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH.

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist, Cardiologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

AIMOVIG

Affected Drugs

AIMOVIG®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The use of at least one standard generic preventative antimigraine therapy (for example, beta blocker (e.g., propranolol, metoprolol, etc.) or antidepressant (e.g., venlafaxine, etc.), or anticonvulsant (e.g., topiramate, divalproex, etc.)) is required prior to initiation of Aimovig unless contraindicated or the member has had an inadequate response.

ALECENSA

Affected Drugs

ALECENSA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of Anaplastic Lymphoma Kinase (ALK)-positive, metastatic Non-Small Cell Lung Cancer (NSCLC) as detected by an FDA-approved test (e.g., FoundationOne CDx). Baseline CPK levels and LFTs (ALT, AST, and total bilirubin).

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ALOSETRON

Affected Drugs

ALOSETRON

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with constipation. In patients with 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 chronic irritable bowel syndrome (presence of diarrhea and one or more of the following: frequent and severe abdominal pain/discomfort, frequent bowel urgency or fecal incontinence, or disability or restriction of daily activities due to IBS) in women with symptoms lasting for at least 6 months without anatomic or biochemical abnormalities of the gastrointestinal tract.

Age Restrictions

N/A

Prescriber Restrictions

Gastroenterologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The documented use of an antispasmodic (e.g., dicylcomine, etc.) or antidiarrheal agent (e.g., loperamide, etc.) is required for current condition prior to the initiation of alosetron.

ALUNBRIG

Affected Drugs

ALUNBRIG™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Alunbrig with strong CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, etc.). Pregnancy in females of reproductive potential.

Required Medical Information

Documented diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer as detected by an FDA-approved test. Baseline Creatine Phosphokinase (CPK) and pancreatic enzymes (e.g., lipase, amylase, etc.).

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

AMBRISENTAN

Affected Drugs

AMBRISENTAN

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential. Idiopathic Pulmonary Fibrosis.

Required Medical Information

Diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1). Baseline hemoglobin.

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist, Cardiologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

APOMORPHINE

Affected Drugs

APOMORPHINE HCL

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of 5HT3 antagonists, including antiemetics (e.g., ondansetron, granisetron, dolasetron, palonosetron, etc.) and alosetron.

Required Medical Information

Documented diagnosis of advanced Parkinson's disease. The member is experiencing breakthrough off periods related to their advanced Parkinson's disease while on current carbidopa/levodopa therapy.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

APREPITANT

Affected Drugs

APREPITANT

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

The use of at least one of the following 5-HT3 antagonists is required prior to the initiation of aprepitant: 1) ondansetron for any FDA-approved indication or 2) granisetron for any FDA-approved indication, except for the prevention of postoperative nausea and vomiting. Part B coverage: 1) If aprepitant is used as full therapeutic replacement for IV anti-emetic drugs within 2 hours prior to administration of the anti-cancer treatment and will not exceed 48 hours after the treatment and 2) If aprepitant is used in combination with a 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, etc.) and dexamethasone and when patient is receiving one or more of the following anti-cancer agents: alemtuzumab, azacitidine, bendamustin, carboplatin, carmustine, cisplatin, clofarabine, cyclophosphamide, cytarabine, dacarbazine, daunorubicin, doxorubicin, epirubicin, idarubicin, ifosfamide, irinotecan, lomustine, mechlorethamine, oxaliplatin, streptozocin.

ARCALYST

Affected Drugs

ARCALYST®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Arcalyst is not administered concurrently with any of the tumor necrosis factor (TNF) blockers (e.g., adalimumab, etanercept, etc.) or IL-1 inhibitors (e.g., ustekinumab, etc.).

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ARMODAFINIL

Affected Drugs

ARMODAFINIL®

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Diagnosis of excessive sleepiness associated with 1) narcolepsy confirmed by a sleep study, 2) obstructive sleep apnea, or 3) shift work disorder or 4) bipolar disorder as an adjunct therapy

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

AUBAGIO

Affected Drugs

AUBAGIO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with severe hepatic impairment. Pregnancy in females of reproductive potential. Concurrent use of leflunomide. In patients with active or chronic infection (e.g., pneumonia, aspergillosis, tuberculosis, etc.).

Required Medical Information

Documented 1) relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and 2) active secondary progressive disease. Recent (e.g., within six months) complete blood count (CBC). Serum ALT less than or equal to 2 times ULN is required prior to the initiation of Aubagio.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

AURYXIA

Affected Drugs

AURYXIA™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of hyperphosphatemia in chronic kidney disease patients on dialysis.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

AUSTEDO

Affected Drugs

AUSTEDO®
AUSTEDO® XR

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Actively suicidal patients, or patients with untreated or inadequately treated depression. Impaired hepatic function. Concurrent use of monoamine oxidase inhibitors, reserpine or tetrabenazine.

Required Medical Information

Documented diagnosis of Huntington's disease chorea or tardive dyskinesia.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist, Psychiatrist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

AVONEX

Affected Drugs

AVONEX ®
AVONEX ADMINISTRATION PACK ®
AVONEX PEN ®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented 1) relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and 2) active secondary progressive disease.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

AYVAKIT

Affected Drugs

AYVAKIT™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Ayvakit with strong CYP3A inducers (e.g., rifampin, etc.) or moderate CYP3A inducers (e.g., efavirenz, etc.).

Required Medical Information

Diagnosis of 1) unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations, or 2) advanced systemic mastocytosis, including aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, or mast cell leukemia, or 3) indolent systemic mastocytosis.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist, Immunologist, Allergy Specialist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

BALVERSA

Affected Drugs

BALVERSA ™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP2C9 inducers (e.g., rifampin, etc.), CYP3A4 inducers (e.g., phenytoin, rifampin, carbamazepine, etc.), or sensitive CYP3A4 substrates with narrow therapeutic indices (e.g., midazolam, triazolam, etc.).

Required Medical Information

Documented diagnosis of locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

BENLYSTA

Affected Drugs

BENLYSTA® 200MG/ML

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Severe active central nervous system lupus or progressive multifocal leukoencephalopathy (PML). Concomitant use with other biologic therapies.

Required Medical Information

Documented diagnosis of 1) active lupus nephritis or 2) active systemic lupus erythematosus (SLE), autoantibody-positive status is confirmed by laboratory testing.

Age Restrictions

N/A

Prescriber Restrictions

Rheumatologist, Nephrologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with SLE, the documented use of at least one standard therapy (e.g., prednisone, methylprednisolone, azathioprine, methotrexate, mycophenolate mofetil, chloroquine, hydroxychloroquine, etc.) is required. In patients with active lupus nephritis, the documented use of at least one standard therapy (e.g., prednisone, methylprednisolone, azathioprine, mycophenolate mofetil, etc.) is required.

B VS D - PART B VERSUS PART D COVERAGE PA

Affected Drugs

ABELCET®
ACETYLCYSTEINE SOLN
ACYCLOVIR SODIUM INJ
ALBUTEROL NEBULIZER
ALBUTEROL SULFATE
AMBISOME®
AMIFOSTINE
AMINOSYN 7% WITH ELECTROLYTES®
AMINOSYN 8.5%-ELECTROLYTES®
AMINOSYN II®
AMINOSYN II 8.5%-ELECTROLYTES®
AMINOSYN-HBC®
AMINOSYN-RF®
AMPHOTERICIN B INJ
ASTAGRAF XL®
AZASAN®
AZATHIOPRINE
BETHKIS®
BROVANA®
BUDESONIDE NEBULIZER
CALCITRIOL CAPS
CELLCEPT®
CINACALCET
CLINISOL SF®
CROMOLYN SODIUM
CYCLOPHOSPHAMIDE
CYCLOSPORINE
CYCLOSPORINE MODIFIED
DOXERCALCIFEROL
ENGERIX-B®
ENVARSUS XR®
EVEROLIMUS (0.25MG, 0.5MG, 0.75MG TABS)
GAMMAGARD LIQUID®
GAMUNEX-C®
GENGRAF
GRANISETRON HCL TABS
HEPARIN SOLN
HEPARIN SOLN IN DEXTROSE

HEPLISAV-B®
IMURAN®
INTRALIPID
IPRATROPIUM BR
IPRATROPIUM-ALBUTEROL
JYNNEOS
KITABIS PAK
LEVALBUTEROL HCL
LEVOCARNITINE INJ
LEVOCARNITINE SOLN
LEVOCARNITINE TABS
MEDROL®
METHYLPREDNISOLONE
MILLIPRED®
MYCOPHENOLATE MOFETIL
MYCOPHENOLIC ACID
MYFORTIC®
NEBUPENT®
NEORAL®
ONDANSETRON ODT
ONDANSETRON HCL ORAL
ORAPRED®
PARICALCITOL
PENTAMIDINE ISETHIONATE
PERFOROMIST®
PLENAMINE™
PREDNISOLONE
PREDNISONE
PREHEVBRIO®
PROGRAF®
PROSOL®
PULMICORT®
PULMOZYME®
RAPAMUNE®
RECOMBIVAX HB SUSP®
RECOMBIVAX HB SYR®
SANDIMMUNE®
SENSIPAR®
SIROLIMUS
TACROLIMUS

TOBI SOLN®
TOBRAMYCIN NEBULIZER
TRAVASOL
TYVASO®
VENTAVIS®
YUPELRI ®
ZORTRESS®

Covered Uses

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.

BESREMI

Affected Drugs

BESREMI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Existence of or history of a severe psychiatric disorder (e.g., severe depression, suicidal ideation or suicide attempt, etc.). Hepatic impairment (Child-Pugh B or C). History or presence of active serious or untreated autoimmune disease. Immunosuppressed transplant recipient. Severe or unstable cardiovascular disease (e.g., uncontrolled hypertension, congestive heart failure (greater than or equal to NYHA class 2), serious cardiac arrhythmia, significant coronary artery stenosis, unstable angina) or recent stroke or myocardial infarction.

Required Medical Information

A documented diagnosis of Polycythemia Vera. Baseline CBC.

Age Restrictions

N/A

Prescriber Restrictions

Hematologist, Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

BETASERON

Affected Drugs

BETASERON®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented 1) relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and 2) active secondary progressive disease.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

BEXAROTENE

Affected Drugs

BEXAROTENE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

In patients requesting oral bexarotene, Liver function tests: ALT/AST, Fasting lipid panel, WBC, thyroid function tests.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist or Dermatologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The patient was prescribed at least one systemic or topical therapy for the current condition prior to the initiation of bexarotene.

BOSENTAN

Affected Drugs

BOSENTAN

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential.

Required Medical Information

Diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) in patients with NYHA Functional Class II-IV symptoms. Baseline LFTs (ALT, AST, bilirubin).

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist, Cardiologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The prior use of sildenafil citrate is required for the current condition in adult patients initiating bosentan.

BOSULIF

Affected Drugs

BOSULIF®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Bosulif will be used in patients with 1) newly-diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML) or 2) chronic, accelerated, or blast phase Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) with resistance or intolerance to prior therapy (e.g. imatinib, dasatinib, or nilotinib, etc.). Baseline CBC and LFTs prior to initiation of Bosulif.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

BRAFTOVI

Affected Drugs

BRAFTOVI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Braftovi with strong or moderate CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, etc.).

Required Medical Information

Diagnosis of 1) unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test (e.g., THXID BRAF Kit, etc.), in combination with binimetinib or 2) metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test (e.g., Qiagen therascreen BRAF V600E RGQ PCR Kit, etc.) after prior therapy (e.g., irinotecan, etc.), in combination with cetuximab. Baseline serum electrolytes (e.g., potassium, magnesium, etc.).

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

BRUKINSA

Affected Drugs

BRUKINSA™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of 1) mantle cell lymphoma in patients who have received at least one prior therapy or 2) Waldenstrom's macroglobulinemia or 3) relapsed or refractory marginal zone lymphoma (MZL) in adult patients who have received at least one anti-CD20-based regimen or 4) chronic lymphocytic leukemia (CLL) or 5) small lymphocytic lymphoma (SLL). Baseline CBC.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

CABOMETYX

Affected Drugs

CABOMETYX™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Recent history of hemorrhage or hemoptysis. Severe hepatic impairment. Severe uncontrolled hypertension.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

CALQUENCE

Affected Drugs

CALQUENCE™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of 1) mantle cell lymphoma who have received at least one prior therapy (e.g., CHOP, cytarabine-based, etc.) or 2) chronic lymphocytic leukemia (CLL) or 3) small lymphocytic lymphoma (SLL). Baseline CBC and ECG.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

CAPRELSA

Affected Drugs

CAPRELSA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Congenital long QT syndrome or QTcF interval greater than 450 ms or history of Torsades de pointes. Caprelsa is concurrently administered with anti-arrhythmic drugs (e.g., amiodarone, disopyramide, procainamide, sotalol, dofetilide, etc.) and other drugs that may prolong the QT interval (e.g., chloroquine, clarithromycin, dolasetron, granisetron, haloperidol, methadone, moxifloxacin, pimozide, etc.)

Required Medical Information

Baseline ECG. The patient's baseline calcium, potassium and magnesium levels are within normal limits.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Endocrinologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

CARGLUMIC ACID

Affected Drugs

CARGLUMIC ACID®

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency, or propionic acidemia (PA), or methylmalonic acidemia (MMA).

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

CAYSTON

Affected Drugs

CAYSTON®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of cystic fibrosis (CF). Pseudomonas Aeruginosa lung infection confirmed by positive culture.

Age Restrictions

Approve if 7 years old or older.

Prescriber Restrictions

Pulmonologist, Infectious Disease Specialist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

CERDELGA

Affected Drugs

CERDELGA ™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Extensive metabolizers (EMs) or intermediate metabolizers (IMs) taking a strong or moderate CYP2D6 inhibitor (e.g., paroxetine, terbinafine, etc.) concomitantly with a strong or moderate CYP3A inhibitor (e.g., ketoconazole, fluconazole, etc.). IMs or poor metabolizers (PMs) taking a strong CYP3A inhibitor (e.g., ketoconazole, etc.). Pre-existing cardiac disease (e.g., congestive heart failure, recent acute myocardial infarction, bradycardia, heart block, ventricular arrhythmia, etc.) or long QT syndrome or concomitant use of Class IA (e.g., quinidine, procainamide, etc.) or Class III (e.g., amiodarone, sotalol, etc.) antiarrhythmic medications.

Required Medical Information

Diagnosis of Gaucher disease type 1 (GD1) confirmed by laboratory or genetic testing. Documentation that the member is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an FDA-approved genotyping test.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

CINRYZE

Affected Drugs

CINRYZE®

Covered Uses

All FDA-approved indications.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Diagnosis of hereditary angioedema (HAE) requiring routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients.

Age Restrictions

Approve if 6 years or older.

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

COMETRIQ

Affected Drugs

COMETRIQ®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with recent history of hemorrhage or hemoptysis. In patients with severe uncontrolled hypertension.

Required Medical Information

Oral examination prior to initiation of Cometriq.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

COPAXONE

Affected Drugs

COPAXONE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented 1) relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and 2) active secondary progressive disease.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

COPIKTRA

Affected Drugs

COPIKTRA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A4 inducers (e.g., phenytoin, rifampin, carbamazepine, etc.)

Required Medical Information

A documented diagnosis of Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies (e.g., ibrutinib, venetoclax, etc.)

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

COSENTYX

Affected Drugs

COSENTYX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with biologic DMARDs (e.g., TNF Antagonists)

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Rheumatologist, Dermatologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with Psoriatic Arthritis, the documented use of at least one conventional Disease-Modifying Anti-Rheumatic Drug (e.g., methotrexate, sulfasalazine, etc.) is required for the current condition prior to the initiation of Cosentyx. In patients with Ankylosing Spondylitis or Non-radiographic Axial Spondyloarthritis or Enthesitis-Related Arthritis, the documented use of at least 1 NSAID is required for the current condition prior to the initiation of Cosentyx. In patients with plaque psoriasis, the documented use of at least one systemic therapy (e.g., methotrexate, cyclosporine, acitretin, etc.) is required prior to the initiation of Cosentyx if a patient is a candidate for systemic therapy. For the indications listed above, the use of at least one prerequisite drug is not required in patients who have already tried a biologic.

COTELLIC

Affected Drugs

COTELLIC ™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

In patients with 1) unresectable or metastatic melanoma with a BRAF V600E or V600K mutation as detected by an FDA-approved test, cotellic is used in combination with Zelboraf (vemurafenib) or 2) histiocytic neoplasms, cotellic is used as a single agent. Baseline LFTs, serum CPK, creatinine levels, and ophthalmic evaluation. Baseline LVEF is greater than 50% confirmed by appropriate methodology (e.g., Echocardiogram, MUGA, MRI, etc.).

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

CRESEMBA

Affected Drugs

CRESEMBA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Co-administration of strong CYP3A4 inhibitors, e.g., ketoconazole or high-dose ritonavir (e.g., 400 mg every 12 hours, etc.) or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, long-acting barbiturates, etc.) with Cresemba. Patients with familial short QT syndrome.

Required Medical Information

Diagnosis of Invasive Fungal Disease, such as invasive aspergillosis or invasive mucormycosis. Baseline liver function tests (AST, ALT, alkaline phosphatase, bilirubin).

Age Restrictions

Approve if 18 years old or older.

Prescriber Restrictions

Infectious Disease Specialist

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

N/A

DALFAMPRIDINE

Affected Drugs

DALFAMPRIDINE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

History of seizures. Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/min).

Required Medical Information

Initiation of dalfampridine: 1) documented diagnosis of multiple sclerosis, and 2) confirmation that patient has difficulty walking (e.g., patient has completed a timed 25-foot walk test, etc.). Reauthorization: confirmation that the patients walking improved with dalfampridine therapy.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

Initial: 3 months. Reauthorization: 12 months.

Other Criteria

N/A

DAURISMO

Affected Drugs

DAURISMO

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A4 inducers (e.g., phenytoin, rifampin, carbamazepine, etc.), or strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, voriconazole, etc.). Concomitant use with drugs that prolong the QTc interval (e.g., amiodarone, disopyramide, procainamide, quinidine, sotalol, etc.).

Required Medical Information

Documented diagnosis of acute myeloid leukemia (AML) in adult patients who are 75 years old or older or adult patients who have comorbidities that preclude use of intensive induction chemotherapy. Used in combination with low-dose cytarabine.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

DEFERASIROX

Affected Drugs

DEFERASIROX

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Platelet count less than 50 x 10(9)/L. Patient with high-risk myelodysplastic syndromes (MDS), advanced malignancies, serum creatinine greater than 2 times the age-appropriate upper limit of normal, creatinine clearance less than 40 mL/min, or severe (Child-Pugh C) hepatic impairment.

Required Medical Information

Baseline serum ferritin and liver function tests (ALT, AST, bilirubin).

Age Restrictions

N/A

Prescriber Restrictions

Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

DEFERIPRONE

Affected Drugs

DEFERIPRONE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias. Baseline absolute neutrophil count (ANC).

Age Restrictions

N/A

Prescriber Restrictions

Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

DIACOMIT

Affected Drugs

DIACOMIT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of seizures associated with Dravet syndrome while on current clobazam therapy.

Age Restrictions

Approve if 6 months of age or older.

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The documented use of at least one formulary anticonvulsant (e.g., valproic acid, topiramate, etc.) for the current condition is required prior to initiation of Diacomit.

DICLOFENAC SODIUM 3% GEL

Affected Drugs

DICLOFENAC SODIUM 3% GEL

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of actinic keratosis. Reauthorization: documented positive clinical response to diclofenac sodium 3% gel therapy.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The documented use of topical fluorouracil or imiquimod is required prior to the initiation of diclofenac sodium 3% gel.

DIMETHYL FUMARATE

Affected Drugs

DIMETHYL FUMARATE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented relapsing forms of multiple sclerosis to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Recent (e.g., within six months) complete blood count (CBC).

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

DRONABINOL

Affected Drugs

DRONABINOL

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

In patients with AIDS, diagnosis of anorexia with weight loss.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

CINV: 6 months. AIDS Anorexia: the PA will be approved through the remainder of the contract year.

Other Criteria

For the treatment of nausea and vomiting associated with cancer chemotherapy, the use of at least one of the following agents is required prior to the initiation of dronabinol: ondansetron, granisetron (or granisol), aprepitant, metoclopramide. Part B coverage: 1) if dronabinol is used as full therapeutic replacement for IV anti-emetic drugs within 2 hours prior to administration of the anti-cancer treatment and will not exceed 48 hours after the treatment. Part D coverage if used after 48 hours of administration of chemotherapy.

DROXIDOPA

Affected Drugs

DROXIDOPA

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Initiation of therapy: a documented diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, pure autonomic failure, etc.), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy. Reauthorization: a documented positive clinical response to therapy (e.g., improvement in dizziness, lightheadedness, etc.).

Age Restrictions

Approve if 18 years old or older.

Prescriber Restrictions

Cardiologist, Neurologist

Coverage Duration

Initiation: 1 month. Reauthorization: Lifetime.

Other Criteria

The documented use of midodrine or fludrocortisone is required prior to the initiation of droxidopa.

DUPIXENT

Affected Drugs

DUPIXENT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody.

Required Medical Information

Documented diagnosis of 1) moderate-to-severe atopic dermatitis whose disease is not adequately controlled or 2) moderate-to-severe asthma characterized by an eosinophilic phenotype or oral corticosteroid dependent asthma, as add-on maintenance treatment or 3) chronic rhinosinusitis with nasal polyposis as add-on maintenance treatment or 4) eosinophilic esophagitis (EoE) in patients weighing at least 40kg or 5) prurigo nodularis.

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist, Dermatologist, Immunologist, Allergy Specialist, Gastroenterologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with refractory, moderate to severe atopic dermatitis, the documented use of at least one topical corticosteroid (e.g., clobetasol propionate, fluocinonide, etc.) or one topical calcineurin inhibitor (e.g., tacrolimus) is required (unless unable to tolerate) prior to initiation of Dupixent. In patients with EoE, the documented use of at least one proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole, etc.) is required (unless unable to tolerate) prior to initiation of Dupixent.

ELIGARD

Affected Drugs

ELIGARD®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In women who are or may become pregnant.

Required Medical Information

Documented diagnosis of advanced prostatic cancer. Baseline electrolytes (e.g., potassium, magnesium, etc.), serum testosterone, PSA, and ECG.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ENBREL

Affected Drugs

ENBREL®
ENBREL MINI®
ENBREL SURECLICK®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with biologic DMARDs (e.g., TNF Antagonists)

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Rheumatologist, Dermatologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with Rheumatoid Arthritis, Polyarticular-Course Juvenile Rheumatoid Arthritis, or Psoriatic Arthritis, the documented use of at least one conventional Disease-Modifying Anti-Rheumatic Drug (e.g., methotrexate, sulfasalazine, etc.) is required for the current condition prior to the initiation of Enbrel. In patients with Ankylosing Spondylitis, the documented use of at least 1 NSAID is required for the current condition prior to the initiation of Enbrel. In patients with plaque psoriasis, the documented use of at least one systemic therapy (e.g., methotrexate, cyclosporine, acitretin, etc.) is required prior to the initiation of Enbrel if a patient is a candidate for systemic therapy. For the indications listed above, the use of at least one prerequisite drug is not required in patients who have already tried a biologic.

EPCLUSA

Affected Drugs

EPCLUSA®

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Epclusa with P-gp inducers or moderate to potent CYP inducers (e.g., rifampin, St. John's wort, carbamazepine, etc.).

Required Medical Information

Diagnosis of chronic hepatitis C virus (HCV) genotypes 1a, 1b, 2, 3, 4, 5, or 6 infection confirmed via detectable serum hepatitis C virus RNA by quantitative assay. Criteria will be applied consistent with current AASLD IDSA guidance.

Age Restrictions

N/A

Prescriber Restrictions

Infectious Disease Specialist, Gastroenterologist, Hepatologist

Coverage Duration

The PA will be approved consistent with current AASLD IDSA guidance.

Other Criteria

Criteria will be applied consistent with current AASLD IDSA guidance.

EPIDIOLEX

Affected Drugs

EPIDIOLEX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of seizures associated with 1) Dravet syndrome or 2) Lennox-Gastaut syndrome or 3) tuberous sclerosis complex. Baseline liver enzymes (e.g., transaminases, etc.) and bilirubin.

Age Restrictions

Approve if 1 year old or older

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The documented use of at least one formulary anticonvulsant (e.g., valproic acid, topiramate, lamotrigine, etc.) is required prior to initiation of Epidiolex.

ERGOLOID MESYLATES

Affected Drugs

ERGOLOID MESYLATES

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with acute or chronic psychosis.

Required Medical Information

N/A

Age Restrictions

Approve if under age 65. If aged 65 years and older, other criteria will apply.

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

A clinical justification for the use of ergoloid mesylates will be required in members 65 years of age and older.

ERIVEDGE

Affected Drugs

ERIVEDGE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A confirmed negative pregnancy test for women of childbearing age prior to initiation of therapy. Confirmed diagnosis of metastatic Basal Cell Carcinoma (BCC) or locally advanced BCC. In a patient with locally advanced BCC, the documentation of BCC recurrence following surgery or radiation is required if a patient is a candidate for surgery or radiation.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Dermatologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ERLEADA

Affected Drugs

ERLEADA™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential. History of seizures.

Required Medical Information

Documented diagnosis of non-metastatic castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer. Concurrent use of Erleada with a gonadotropin-releasing hormone (GnRH) analog unless the patient has had a bilateral orchiectomy.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Urologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ERLOTINIB

Affected Drugs

ERLOTINIB

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Covered Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of 1) 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 or 2) locally advanced, unresectable, or metastatic pancreactic cancer. In patients with pancreatic cancer, erlotinib will be used in combination with gemcitabine. Baseline serum electrolytes (e.g., potassium, magnesium, etc.), renal function test (e.g., SCr, BUN, etc), and LFTs (e.g., ALT, AST, etc.)

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ESBRIET

Affected Drugs

ESBRIET®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Severe hepatic impairment (Child-Pugh Class C). End stage renal disease (ESRD) requiring dialysis.

Required Medical Information

Confirmed diagnosis of idiopathic pulmonary fibrosis (e.g., via high-resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP), etc.). Baseline liver function tests: ALT, AST, bilirubin.

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ESTROGENS

Affected Drugs

AMABELZ™
ALORA®
ESTRADIOL TABS/TRANSDERMAL
ESTRADIOL/NORETHINDRONE
ESTROPIPATE
FYAVOLV
JINTELI
MENEST®
MIMVEY®
MIMVEY LO®
PREMARIN ORAL®
PREMPHASE®
PREMPRO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

Approve if under age 65. If aged 65 years and older, other criteria will apply.

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

A clinical justification for the use of estrogens will be required in members 65 years of age and older.

EVEROLIMUS

Affected Drugs

EVEROLIMUS (2.5MG, 5MG, 7.5MG, 10MG TABS)

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Co-administered with P-gp and strong CYP3A4 inhibitors, such as ketoconazole.

Required Medical Information

In patients with renal angiomyolipoma and tuberous sclerosis complex (TSC), a documentation that no immediate surgery is required. In patients with progressive neuroendocrine tumors (PNET) of pancreatic origin and progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal or lung origin, absence of functional carcinoid tumors and a documentation of unresectable, locally advanced or metastatic disease. In patients with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) and require therapeutic intervention, a documentation of unresectable disease. CBC, SrCr, BUN, serum glucose, lipid panel.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

For the treatment of advanced renal cell carcinoma, the documented use of sunitinib or sorafenib or both is required prior to the initiation of everolimus. For the treatment of advanced hormone receptor-positive, HER2-negative breast cancer in postmenopausal women, everolimus will be used in combination with exemastane after failure of treatment with letrozole or anastrozole.

EVEROLIMUS SOLUBLE TABLET

Affected Drugs

EVEROLIMUS (2MG, 3MG, 5MG TABS FOR SUSP)

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Everolimus soluble tablet is co-administered with strong inhibitors of CYP3A4 (e.g., ketoconazole, itraconazole, etc.).

Required Medical Information

CBC, SrCr, BUN, serum glucose, lipid panel.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

EXKIVITY

Affected Drugs

EXKIVITY™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Interstitial Lung Disease, Pneumonitis. Concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, etc.). Concomitant use with strong CYP3A inducers (e.g., rifampin, etc.) or moderate CYP3A inducers (e.g., efavirenz, etc.).

Required Medical Information

Documented diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

FASENRA

Affected Drugs

FASENRA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody. Being used as a single agent.

Required Medical Information

A documented diagnosis of severe asthma with an eosinophilic phenotype. Baseline blood eosinophil level greater than or equal to 150 cells per microliter.

Age Restrictions

12 years or older

Prescriber Restrictions

Pulmonologist, Immunologist, Allergy Specialist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The member has been unable to achieve adequate asthma control while on maximum tolerated inhaled corticosteroid therapy in combination with a long acting beta agonist unless contraindicated. For current Fasenra users, the member is stable on therapy and will continue on asthma controller inhalers.

FENTANYL CITRATE TRANSMUCOSAL

Affected Drugs

FENTANYL CITRATE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Management of acute, intermittent or postoperative pain. Opioid naive patients, such as patients who are not taking at least 60 mg morphine per day, or 25 mcg transdermal fentanyl per hour, or 30 mg oxycodone per day, or 8 mg oral hydromorphone daily, or an equianalgesic dose of another opioid for a week or longer.

Required Medical Information

Documented history of Opioid use.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Pain Specialist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

FERRIPROX

Affected Drugs

FERRIPROX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias. Baseline absolute neutrophil count (ANC).

Age Restrictions

N/A

Prescriber Restrictions

Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

FINGOLIMOD

Affected Drugs

FINGOLIMOD

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with a recent (i.e., within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. Baseline QTc interval greater than or equal to 500 ms. Treatment with Class Ia or Class III anti-arrhythmic drugs (e.g., quinidine, procainamide, disopyramide, sotalol, amiodarone, etc.). In patients with active or chronic infection (e.g., pneumonia, disseminated primary herpes zoster, herpes simplex encephalitis, etc.).

Required Medical Information

Documented diagnosis of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease. Baseline ECG, recent CBC (i.e., within the last 6 months), recent (i.e., within the last 6 months) liver enzymes: transaminase and bilirubin levels, and an ophthalmologic evaluation prior to initiation of fingolimod.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

FINTEPLA

Affected Drugs

FINTEPLA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome.

Age Restrictions

Approve if 2 years old or older.

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The documented use of at least one formulary anticonvulsant (e.g., valproic acid, topiramate, etc.) for the current condition is required prior to initiation of Fintepla.

FORTEO

Affected Drugs

FORTEO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Patients have increased baseline risk for osteosarcoma (e.g., those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton).

Required Medical Information

Documented history of one of the following: 1. The patient is at high risk for fractures (BMD T score below -2.5, steroids use) or has a history of an osteoporotic fracture. 2. The patient had a fracture and/ or experienced a decrease in BMD T score while on either alendronate, risedronate, and ibandronate. 3. The patient is not a candidate for bisphosphonates or intolerant to them.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for 2 years.

Other Criteria

N/A

FOTIVDA

Affected Drugs

FOTIVDA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of strong CYP3A inducers (e.g., rifampin, etc.). Severe arterial thromboembolic event (e.g., myocardial infarction, stroke, etc.). Severe hemorrhagic event.

Required Medical Information

Documented relapsed or refractory advanced renal cell carcinoma (RCC) following at least two prior systemic therapies.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

GATTEX

Affected Drugs

GATTEX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with active gastrointestinal malignancy (e.g., GI tract, hepatobiliary, pancreatic, or colorectal cancer).

Required Medical Information

A documented diagnosis of Short Bowel Syndrome (SBS) in adults and pediatric patients 1 year of age and older dependent on parenteral nutrition for at least 12 months. Baseline bilirubin, alkaline phosphatase, lipase, and amylase tests.

Age Restrictions

N/A

Prescriber Restrictions

Gastroenterologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

GAVRETO

Affected Drugs

GAVRETO™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of 1) metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test or 2) advanced or metastatic RET fusion-positive thyroid cancer that requires systemic therapy and is radioactive iodine-refractory (if radioactive iodine is appropriate). Baseline ALT, AST.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

GEFITINIB

Affected Drugs

GEFITINIB

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

GENOTROPIN

Affected Drugs

GENOTROPIN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with Acute Critical Illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure. In children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment. In patients with Active Malignancy. In Patients with Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy. In children with closed epiphyses.

Required Medical Information

Diagnoses of Prader-Willi syndrome and Turner Syndrome are confirmed by genetic testing. Idiopathic short stature is confirmed by height less or equal to 2.25 SD (standard deviation) below the mean height for age and the diagnostic evaluation excludes other causes of short stature that should be treated by other means. Diagnosis of growth failture due to inadequate secretion of endogenous growth hormone. Diagnosis of short stature born small for gestational age with no catch-up growth by 2 years of age. In adults with Growth Hormone Deficiency, IGF-1 level of less than 84 ng/ml or Growth hormone stimulation tests, e.g., insulin tolerance test (ITT) with GH level of less than 5 mcg/L, GHRH with arginine with GH level of less than 4.1 mcg/L.

Age Restrictions

N/A

Prescriber Restrictions

Endocrinologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

GILENYA

Affected Drugs

GILENYA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with a recent (i.e., within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. Baseline QTc interval greater than or equal to 500 ms. Treatment with Class Ia or Class III anti-arrhythmic drugs (e.g., quinidine, procainamide, disopyramide, sotalol, amiodarone, etc.). In patients with active or chronic infection (e.g., pneumonia, disseminated primary herpes zoster, herpes simplex encephalitis, etc.).

Required Medical Information

Documented 1) relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and 2) active secondary progressive disease. Baseline ECG, recent CBC (i.e., within the last 6 months), recent (i.e., within the last 6 months) liver enzymes: transaminase and bilirubin levels, and an ophthalmologic evaluation prior to initiation of Gilenya.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

GILOTRIF

Affected Drugs

GILOTRIF®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of 1) metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions, exon 21 (L858R), L861Q, G719X or S768I substitution mutations as detected by an FDA-approved test (e.g., the therascreen EGFR RGQ PCR Kit, etc.) OR 2) metastatic, squamous NSCLC that has progressed after platinum-based chemotherapy.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

GLATIRAMER

Affected Drugs

GLATIRAMER

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented 1) relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and 2) active secondary progressive disease.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

GLATOPA

Affected Drugs

GLATOPA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented 1) relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and 2) active secondary progressive disease.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

HARVONI

Affected Drugs

HARVONI®

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Diagnosis of hepatitis C infection confirmed via detectable serum hepatitis C virus RNA by quantitative assay. Criteria will be applied consistent with current AASLD IDSA guidance.

Age Restrictions

N/A

Prescriber Restrictions

Infectious Disease Specialist, Gastroenterologist, Hepatologist

Coverage Duration

The PA will be approved consistent with current AASLD IDSA guidance.

Other Criteria

Criteria will be applied consistent with current AASLD IDSA guidance.

HETLIOZ

Affected Drugs

HETLIOZ®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Severe hepatic impairment (Child-Pugh Class C). Co-administration of Hetlioz with strong CYP1A2 inhibitors (e.g., fluvoxamine, etc.) or strong CYP3A4 inducers (e.g., rifampin, etc.).

Required Medical Information

A documented diagnosis of 1) Non-24-Hour Sleep-Wake Disorder (Non-24) as defined by the International Classification of Sleep Disorders in a totally blind patient with no perception of light or 2) Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).

Age Restrictions

N/A

Prescriber Restrictions

Sleep Specialist or Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

HUMATROPE

Affected Drugs

HUMATROPE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with Acute Critical Illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure. In children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment. In patients with Active Malignancy. In Patients with Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy. In children with closed epiphyses.

Required Medical Information

Diagnoses of Turner Syndrome or SHOX deficiency are confirmed by genetic testing. Idiopathic short stature is confirmed by height less or equal to 2.25 SD (standard deviation) below the mean height for age and the diagnostic evaluation excludes other causes of short stature that should be treated by other means. Diagnosis of growth failture due to inadequate secretion of endogenous growth hormone. Diagnosis of short stature born small for gestational age with no catch-up growth by 2 years to 4 years of age. In adults with Growth Hormone Deficiency, IGF-1 level of less than 84 ng/ml or Growth hormone stimulation tests, e.g., insulin tolerance test (ITT) with GH level of less than 5 mcg/L, GHRH with arginine with GH level of less than 4.1 mcg/L.

Age Restrictions

N/A

Prescriber Restrictions

Endocrinologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

HUMIRA

Affected Drugs

HUMIRA®
HUMIRA PEDIATRIC CROHNS®
HUMIRA PEN®
HUMIRA PEN-CD/UC/HS STARTER®
HUMIRA PEN-PS/UV STARTER®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with biologic DMARDs (e.g., TNF Antagonists)

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Rheumatologist, Dermatologist, Gastroenterologist, Ophthalmologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with Rheumatoid Arthritis, Polyarticular-Course Juvenile Rheumatoid Arthritis, or Psoriatic Arthritis, the documented use of at least one conventional Disease-Modifying Anti-Rheumatic Drug (e.g., methotrexate, sulfasalazine, etc.) is required for the current condition prior to the initiation of Humira. In patients with Ankylosing Spondylitis, the documented use of at least 1 NSAID is required for the current condition prior to the initiation of Humira. In patients with plaque psoriasis, the documented use of at least one systemic therapy (e.g., methotrexate, cyclosporine, acitretin, etc.) is required prior to the initiation of Humira if a patient is a candidate for systemic therapy. In patients with Crohn's disease, the documented use of at least one conventional therapy agent (e.g., 6-mercaptopurine, azathioprine, etc.) is required prior to the

initiation of Humira. In patients with moderately to severely active ulcerative colitis, the documented use of at least one conventional therapy agent (e.g., a corticosteroid, azathioprine, or 6-mercaptopurine, etc.) is required prior to initiation of Humira. For the indications listed above, the use of at least one prerequisite drug is not required in patients who have already tried a biologic.

IBRANCE

Affected Drugs

IBRANCE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer confirmed via testing. Ibrance will be used in combination with an 1) aromatase inhibitor (e.g., letrozole, etc.) as initial endocrine-based therapy in pre/perimenopausal or postmenopausal women or in men OR 2) fulvestrant in patients with disease progression following endocrine therapy. Baseline CBC.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ICATIBANT

Affected Drugs

ICATIBANT

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of hereditary angioedema (HAE). The patient (or a caregiver) has received training from a healthcare provider on how to self-administer icatibant.

Age Restrictions

Approve if 18 years or older.

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ICLUSIG

Affected Drugs

ICLUSIG®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) or T315I-positive chronic phase, accelerated phase, or blast phase CML confirmed by testing or T315I-positive Ph+ ALL confirmed by testing. Baseline CBC, LFTs, and eye examination prior to initiation of Iclusig.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

A documented resistance and/or intolerance to at least one prior tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, nilotinib, bosutinib, etc.) is required prior to initiation of Iclusig (a trial of at least one prior tyrosine kinase inhibitor therapy is not required if a patient has T315I-positive chronic phase, accelerated phase, or blast phase CML or T315I-positive Ph+ ALL).

ICOSAPENT ETHYL

Affected Drugs

ICOSAPENT ETHYL

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with hypertriglyceridemia, a documented use of omega-3 acid ethyl esters is required prior to initiation of Icosapent Ethyl.

IDHIFA

Affected Drugs

IDHIFA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential.

Required Medical Information

Documented diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA approved test (e.g., RealTime IDH2, etc.) Baseline CBC, bilirubin and uric acid level.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

IMATINIB

Affected Drugs

IMATINIB MESYLATE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of 1) Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase or 2) Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy or 3) relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) or 4) newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy in pediatric patients or 5) myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements or 6) aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown or 7) hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) or 8) unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) or 9) Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST) or 10) Adjuvant treatment following resection of Kit (CD117) positive GIST).

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Allergist, Immunologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

IMBRUVICA

Affected Drugs

IMBRUVICA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of Waldenstrom's macroglobulinemia (WM) or chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) or chronic lymphocytic leukemia (CLL) with 17p deletion or small lymphocytic lymphoma (SLL) with 17p deletion or chronic graft versus host disease

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist, Transplant specialist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

A documented use of at least one line systemic therapy (e.g. corticosteroid, etc.) for chronic graft versus host disease is required prior to the initiation of Imbruvica.

INCRELEX

Affected Drugs

INCRELEX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with secondary forms of IGF-1 deficiency, such as Growth Hormone (GH) deficiency, malnutrition, hypothyroidism, and chronic treatment with pharmacologic doses of anti-inflammatory steroids. In patients with closed epiphyses. In patients with active or suspected neoplasia. In adult patients.

Required Medical Information

In growth failure patients with Severe Primary IGF-1 deficiency, Severe Primary IGF-1 deficiency is defined by: height standard deviation score is 3.0 or less and basal IGF-1 standard deviation score is 3.0 or less and normal or elevated GH. In growth failure patients with GH gene deletion who have developed neutralizing antibodies to GH, the diagnosis must be confirmed by Laboratory or Genetic testing.

Age Restrictions

Approve in children 2 years old and older

Prescriber Restrictions

Endocrinologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

INLYTA

Affected Drugs

INLYTA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Arterial thromboembolic event (e.g., transient ischemic attack, cerebrovascular accident, myocardial infarction, retinal artery occlusion, etc.) within the previous 12 months. Venous thromboembolic event (e.g., pulmonary embolism, deep vein thrombosis, retinal vein occlusion, retinal vein thrombosis, etc.) within the previous 6 months. Untreated brain metastasis. Recent active gastrointestinal bleeding. Reversible posterior leukoencephalopathy syndrome with previous Inlyta treatment. Severe hepatic impairment. Scheduled surgery within the next 24 hours.

Required Medical Information

Inlyta will be used 1) in combination with avelumab, for the first-line treatment in patients with advanced renal cell carcinoma (RCC), or 2) in combination with pembrolizumab, for the first-line treatment in patients with advanced RCC or 3) as a single agent, for the treatment in patients with advanced RCC after a trial of at least one prior systemic therapy (e.g., sunitinib, temsirolimus, pazopanib, interleukin-2 (IL-2), sorafenib, everolimus, etc.). Documented well-controlled blood pressure prior to initiating Inlyta. Baseline thyroid function tests, baseline liver function tests (AST, ALT, bilirubin) and baseline test to monitor for proteinuria are required prior to initiation of Inlyta.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

INQOVI

Affected Drugs

INQOVI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of 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. Baseline CBC.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

INREBIC

Affected Drugs

INREBIC®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis.

Age Restrictions

N/A

Prescriber Restrictions

Hematologist, Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

IRESSA

Affected Drugs

IRESSA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

JAKAFI

Affected Drugs

JAKAFI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

The diagnosis of 1) intermediate or high-risk myelofibrosis (including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis) or 2) polycythemia vera or 3) steroid-refractory acute graft-versus-host disease or 4) chronic graft-versus-host disease after failure of at least one line of systemic therapy. Baseline CBC, liver and renal function tests. The platelet count is equal to or greater than 50 X 10(9)/L.

Age Restrictions

Acute and chronic graft-versus-host disease: 12 years and older.

Prescriber Restrictions

Hematologist, Oncologist, Transplant Specialist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with polycythemia vera, a documented inadequate response or intolerance to hydroxyurea is required prior to initiation of Jakafi.

JAYPIRCA

Affected Drugs

JAYPIRCA™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a BTK inhibitor. Baseline CBC.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

JUXTAPID

Affected Drugs

JUXTAPID®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy. In patients with moderate or severe hepatic impairment (based on Child-Pugh category B or C) and in patients with active liver disease, including unexplained persistent elevations of serum transaminases. Concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, ketoconazole, posaconazole, ritonavir, voriconazole, etc.) or moderate CYP3A4 inhibitors (e.g., ciprofloxacin, diltiazem, erythromycin, fluconazole, verapamil, etc.).

Required Medical Information

A documented diagnosis of homozygous familial hypercholesterolemia in patients with LDL-R genetic mutations confirmed by genetic testing or clinical criteria: 1) untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL or 2) patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma). Inadequate response to a lipid-lowering therapy containing a high potency statin, unless a patient is intolerant to statin. Juxtapid is being used as an adjunct to a lipid lowering therapy containing a high potency statin. Baseline LFTs (ALT, AST, alkaline phosphatase, total bilirubin). Reauthorization: a documented positive clinical response to Juxtapid.

Age Restrictions

Approve if 18 years old or older.

Prescriber Restrictions

N/A

Coverage Duration

Initiation: 6 months. Reauthorization: 12 months.

Other Criteria

N/A

KALYDECO

Affected Drugs

KALYDECO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Kalydeco is used concomitantly with strong CYP3A inducers (e.g., rifampin, etc.). Patient is homozygous for the F508del mutation in the CFTR gene.

Required Medical Information

A documented diagnosis of cystic fibrosis (CF) in patients who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation (if the patient's genotype is unknown, an FDA-cleared CF mutation test will be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use). Baseline liver function tests (AST, ALT).

Age Restrictions

Approve if 1 month or older.

Prescriber Restrictions

Pulmonologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

KINERET

Affected Drugs

KINERET®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Known hypersensitivity to E coli-derived proteins, Kineret, or to any component of the product. Concurrent use with any live vaccines. In patients with active infections (e.g., upper respiratory tract infections, tuberculosis, etc.) or used in combination with any tumor necrosis factor (TNF) blocking agents (e.g., adalimumab, etanercept, infliximab, etc.).

Required Medical Information

In patients with rheumatoid arthritis (RA), a diagnosis of moderately to severely active RA. In patients with Cryopyrin-Associated Periodic Syndromes (CAPS), a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID). Baseline neutrophil count. The patient (or a caregiver) has received training from a healthcare provider on how to self-administer Kineret.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with moderately to severely active rheumatoid arthritis, the documented use of at least one disease modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, etanercept, adalimumab, etc.) is required prior to the initiation of Kineret.

KISQALI

Affected Drugs

KISQALI®
KISQALI® FEMARA® CO-PACK

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Kisqali with strong CYP3A4 inducers (e.g., phenytoin, rifampin, carbamazepine, etc.). Patients who already have or who are at significant risk of developing QTc prolongation, including patients with: long QT syndrome, uncontrolled or significant cardiac disease (including recent myocardial infarction, congestive heart failure, unstable angina and bradyarrhythmias), electrolyte abnormalities, or concomitant use with drugs that prolong the QT interval (e.g., amiodarone, disopyramide, procainamide, quinidine, sotalol, etc.).

Required Medical Information

Documented diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. Kisqali will be used in combination with 1) an aromatase inhibitor (e.g., letrozole, etc.) as initial endocrine-based therapy in pre/perimenopausal or postmenopausal women or in men OR 2) fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy (e.g., letrozole, exemestane, etc.) in postmenopausal women or in men. Baseline LFTs, CBC, ECG, and electrolytes.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

KORLYM

Affected Drugs

KORLYM®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential. Use of simvastatin, lovastatin, and CYP3A substrates with narrow therapeutic range (e.g., cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus, etc.). In women with history of unexplained vaginal bleeding. In women with endometrial hyperplasia with atypia or endometrial carcinoma. In patients who require concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses (e.g., immunosuppression after organ transplantation).

Required Medical Information

A documented diagnosis of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

Age Restrictions

N/A

Prescriber Restrictions

Endocrinologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

KRAZATI

Affected Drugs

KRAZATI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A4 inducers (e.g., rifampin, etc.). Interstitial Lung Disease (ILD) or Pneumonitis.

Required Medical Information

Documented diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test (e.g., therascreen KRAS RGQ PCR Kit, Agilent Resolution ctDx FIRST assay, etc.), who have received at least one prior systemic therapy. Baseline LFTs.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

LAPATINIB

Affected Drugs

LAPATINIB

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Laboratory testing based on the new HER2 Testing Guidelines from the College of American Pathologists (CAP) and the American Society of Clinical Oncology (ASCO) that confirms Human Epidermal Receptor Type 2 (HER2) overexpression in the patient's tumor. Testing for hormone receptor positive metastatic breast cancer in postmenopausal women who will be prescribed lapatinib with letrozole. The patient's baseline LVEF, baseline potassium and magnesium levels are within normal limits. Liver function tests: ALT, AST, bilirubin.

Age Restrictions

N/A

Prescriber Restrictions

The prescription must be initially written or recommended by the Oncologist.

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The documented use of anthracycline, taxane, and trastuzumab is required prior to the initiation of lapatinib with advanced or metastatic breast cancer who will receive lapatinib in combination with capecitabine. These criteria do not apply for the other indication: in postmenopausal women with hormone receptor positive metastatic breast cancer who will receive lapatinib in combination with letrozole.

LEDIPASVIR-SOFOSBUVIR

Affected Drugs

LEDIPASVIR-SOFOSBUVIR

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Diagnosis of hepatitis C infection confirmed via detectable serum hepatitis C virus RNA by quantitative assay. Criteria will be applied consistent with current AASLD IDSA guidance.

Age Restrictions

N/A

Prescriber Restrictions

Infectious Disease Specialist, Gastroenterologist, Hepatologist

Coverage Duration

The PA will be approved consistent with current AASLD IDSA guidance.

Other Criteria

Criteria will be applied consistent with current AASLD IDSA guidance.

LENALIDOMIDE

Affected Drugs

LENALIDOMIDE

Covered Uses

All FDA-approved Indications not otherwise excluded from Part D and some other medically accepted indications listed below under Off Label Uses field.

Off-label Uses

Treatment of multiple myeloma following autologous hematopoietic stem cell transplantation, previously treated follicular lymphoma, or previously treated marginal zone lymphoma

Exclusion Criteria

Pregnancy in females of reproductive potential.

Required Medical Information

Lenalidomide will not be used in patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials. A documented diagnosis of 1) transfusion-dependent anemia due to low-or intermediate-1-risk myelodysplastic syndromes (MDS), where disease is associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities confirmed by testing, 2) multiple myeloma for combination use with dexamethasone, 3) multiple myeloma as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT), 4) mantle cell lymphoma, 5) previously treated follicular lymphoma for combination use with a rituximab product, 6) previously treated marginal zone lymphoma for combination use with a rituximab product.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist.

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with mantle cell lymphoma (MCL), documented disease relapse or progression on at least two prior therapies including bortezomib is required prior to the initiation of lenalidomide.

LENVIMA

Affected Drugs

LENVIMA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Lenvima will be used 1) in patients with differentiated thyroid cancer, disease is locally recurrent or metastatic, progressive, and refractory to radioactive iodine treatment or 2) in patients with advanced renal cell cancer, as the first line treatment, in combination with pembrolizumab or 3) in patients with advanced renal cell cancer, Lenvima will be used in combination with everolimus following one prior anti-angiogenic therapy or 4) in patients with unresectable hepatocellular carcinoma or 5) in patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), Lenvima will be used in combination with pembrolizumab for patients who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

LEUKINE

Affected Drugs

LEUKINE®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with excessive leukemic myeloid blasts in the bone marrow or peripheral blood (equal to or greater than 10%). Concomitant use with chemotherapy and radiotherapy.

Required Medical Information

CBC with differential (including examination for the presence of blast cells).

Age Restrictions

Approve if 55 years old or older in patients with Acute Myelogenous Leukemia.

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

Leukine is subject to Part B vs. Part D determination.

LIDOCAINE PATCH

Affected Drugs

LIDOCAINE PATCH

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

N/A

LONSURF

Affected Drugs

LONSURF®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Confirmed diagnosis of 1) metastatic colorectal cancer when Lonsurf is used as a single agent or in combination with bevacizumab or 2) metastatic gastric or gastroesophageal junction adenocarcinoma. Baseline complete blood count (CBC) and platelet count.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with colorectal cancer, the documented use of fluoropyrimidine-oxaliplatin-irinotecan-based therapy, an anti-VEGF biological therapy, and, if RAS wild-type, an anti-EGFR therapy are required prior to the initiation of Lonsurf. In patients with metastatic gastric or gastroesophageal junction adenocarcinoma, the documented use of at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy are required prior to the initiation of Lonsurf.

LORBRENA

Affected Drugs

LORBRENA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A4 inducers (e.g., rifampin, etc.). Interstitial lung disease or Pneumonitis.

Required Medical Information

Documented diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test (e.g., VENTANA ALK (D5F3) CDx Assay, etc.).

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

LUMAKRAS

Affected Drugs

LUMAKRAS™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A4 inducers (e.g., rifampin, etc.). Interstitial Lung Disease (ILD) or Pneumonitis.

Required Medical Information

Documented diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test (e.g., therascreen KRAS RGQ PCR Kit, Guardant360® CDx, etc.), who have received at least one prior systemic therapy. Baseline LFTs (ALT, AST, and total bilirubin).

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

LUPRON DEPOT

Affected Drugs

LUPRON DEPOT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In women who are or may become pregnant, or who are breastfeeding. Undiagnosed abnormal vaginal bleeding.

Required Medical Information

Documented diagnosis of 1) advanced prostatic cancer 2) endometriosis (including pain relief, reduction of endometriotic lesion, and recurrence of symptoms) or 3) uterine leiomyomata. In patients with advanced prostatic cancer, baseline serum testosterone, PSA.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

LUPRON DEPOT PED

Affected Drugs

LUPRON DEPOT PED®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy

Required Medical Information

Documented diagnosis of central precocious puberty.

Age Restrictions

Approve if a pediatric patient 1 years of age or older.

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

LYBALVI

Affected Drugs

LYBALVI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of opioids. Patients undergoing acute opioid withdrawal.

Required Medical Information

Documented diagnosis of 1) schizophrenia or 2) bipolar I disorder: as maintenance monotherapy treatment or acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate. Baseline CBC.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

LYNPARZA

Affected Drugs

LYNPARZA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis with mutations as detected by an FDA-approved test (e.g., BRACAnalysis CDx, etc.), where applicable, based on the FDA-approved indication.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

LYTGOBI

Affected Drugs

LYTGOBI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with dual P-gp and strong CYP3A inhibitors (e.g., itraconazole, etc.) and dual P-gp and strong CYP3A inducers (e.g., rifampin, etc.).

Required Medical Information

Documented diagnosis of previously treated unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements, confirmed by next generation sequencing. Baseline phosphate levels.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

MEKINIST

Affected Drugs

MEKINIST®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with colorectal cancer, interstitial lung disease or pneumonitis.

Required Medical Information

A documented diagnosis of (1) unresectable or metastatic melanoma with BRAF V600E or V600K mutation as detected by an FDA-approved test (e.g., the THxID BRAF kit, etc.), (2) metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test (e.g., Oncomine Dx Target Test, etc.), (3) locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options, (4) adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test and involvement of lymph node(s) following complete resection, (5) unresectable or metastatic solid tumors with BRAF V600E mutation in patients who have progressed following prior treatment and have no satisfactory alternative treatment options, or (6) low-grade glioma (LGG) with a BRAF V600E mutation requiring systemic therapy. In patients with NSCLC, or ATC, or unresectable or metastatic solid tumors, or as adjuvant treatment in patients with melanoma, or LGG, Mekinist will be used in combination with dabrafenib (Tafinlar). Baseline left ventricular ejection fraction obtained via ECHO or MUGA. Baseline ophthalmologic evaluation.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

MEKTOVI

Affected Drugs

MEKTOVI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test (e.g., Oncomine Dx Target Test, etc.), in combination with encorafenib. Baseline LFTs, serum CPK, creatinine levels, and ophthalmic evaluation.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

METHYLDOPA

Affected Drugs

METHYLDOPA

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

Approve if under age 65. If aged 65 years and older, other criteria will apply.

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

A clinical justification for the use of methyldopa will be required in members 65 years of age and older.

METYROSINE

Affected Drugs

METYROSINE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of pheochromocytoma. Metyrosine will not be used in patients for the treatment of essential hypertension.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

MIGLUSTAT

Affected Drugs

MIGLUSTAT

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

The diagnosis must be confirmed by laboratory or Genetic testing. Documented intolerance to Enzyme Replacement Therapy, such as allergy, hypersensitivity, or poor venous access.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

MODAFINIL

Affected Drugs

MODAFINIL

Covered Uses

All FDA-approved Indications not otherwise excluded from Part D and some other medically accepted indications listed below under Off Label Uses field.

Off-label Uses

Treatment of idiopathic hypersomnia.

Exclusion Criteria

N/A

Required Medical Information

Diagnosis of excessive sleepiness associated with 1) narcolepsy confirmed by a sleep study, 2) obstructive sleep apnea, or 3) shift work disorder, or 4) diagnosis of Idiopathic Hypersomnia confirmed by a sleep study as defined by the International Classification of Sleep Disorders.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

NATPARA

Affected Drugs

NATPARA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with hypoparathyroidism caused by calcium sensing receptor mutations, acute post-surgical hypoparathyroidism, or increased baseline risk for osteosarcoma (e.g., patients with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with hereditary disorders predisposing to osteosarcoma, patients with a history of prior external beam or implant radiation therapy involving the skeleton, etc.).

Required Medical Information

A documented diagnosis of hypocalcemia in patients with hypoparathyroidism as an adjunct to calcium and vitamin D supplementation. Serum calcium level is above 7.5mg/dL and 25-hydroxyvitamin D concentration is above 20ng/mL (50nmol/L).

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

NERLYNX

Affected Drugs

NERLYNX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Nerlynx with strong CYP3A4 inducers (e.g., phenytoin, rifampin, carbamazepine, etc.), or strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, voriconazole, etc.). In patients experiencing Grade 3 or Grade 4 liver abnormalities. In women who are or may become pregnant, or who are breastfeeding.

Required Medical Information

A documented diagnosis of 1) early stage HER2-overexpressed/amplified breast cancer or 2) advanced or metastatic HER2-positive breast cancer. In patients with advanced or metastatic HER2-positive breast cancer, Nerlynx will be used in combination with capecitabine. Baseline LFTs.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with early stage HER2-positive breast cancer, the documented treatment with trastuzumab based therapy is required prior to the initiation of Nerlynx. In patients with advanced or metastatic HER2-positive breast cancer, the documented use of at least two anti-HER2 based regimens is required prior to the initiation of Nerlynx.

NINLARO

Affected Drugs

NINLARO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of multiple myeloma. Ninlaro will be used in combination with lenalidomide and dexamethasone. Baseline absolute neutrophil count is equal to or greater than 1,000/mm3. Baseline platelet count is equal to or greater than 75,000/mm3.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

At least one prior therapy (e.g., bortezomib, thalidomide, etc.) is required prior to the initiation of Ninlaro.

NITISINONE

Affected Drugs

NITISINONE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

The diagnosis must be confirmed by laboratory or genetic testing.

Age Restrictions

N/A

Prescriber Restrictions

The prescription is recommended or initially written by gastroenterologist, hematologist, metabolic specialist, nephrologist or other specialist experienced in the treatment of Hereditary Tyrosinemia type 1.

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

NIVESTYM

Affected Drugs

NIVESTYM

Covered Uses

All FDA-approved Indications not otherwise excluded from Part D and some other medically accepted indications listed below under Off Label Uses field.

Off-label Uses

Treatment of graft failure after bone marrow transplantation, neutropenia associated with myelodysplastic syndrome, hairy cell leukemia, aplastic anemia, severe neutropenia in HIV-infected patients on antiretroviral therapy

Exclusion Criteria

N/A

Required Medical Information

Baseline complete blood count (CBC) and platelet count.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist, or Infectious Disease Specialist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

NOXAFIL SUSP

Affected Drugs

NOXAFIL® SUSP

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concurrent use of any of the following with Noxafil: sirolimus, pimozide, quinidine, HMG-CoA reductase inhibitors primarily metabolized through CYP3A4 (e.g., atorvastatin, lovastatin, or simvastatin), or ergot alkaloids (e.g., ergotamine or dihydroergotamine).

Required Medical Information

For prevention of invasive Aspergillus and Candida infections, documentation is required that the patients are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Age Restrictions

Approve if 13 years old or older.

Prescriber Restrictions

Infectious Disease Specialist, Oncologist, Transplant Specialist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The documented use of itraconazole or fluconazole is required prior to the initiation of Noxafil in patients with refractory oropharyngeal candidiasis.

NUBEQA

Affected Drugs

NUBEQA

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria

Concomitant use with combined P-gp and strong or moderate CYP3A inducers (e.g., rifampicin, etc.).

Required Medical Information

Documented diagnosis of 1) non-metastatic castration-resistant prostate cancer or 2) metastatic hormone-sensitive prostate cancer in combination with docetaxel. Concurrent use of Nubeqa with a gonadotropin-releasing hormone (GnRH) analog unless the patient has had a bilateral orchiectomy.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Urologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

NUEDEXTA

Affected Drugs

NUEDEXTA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria

Concomitant use with quinidine, quinine, or mefloquine or MAOI. In patients with a history of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions. In patients with prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, heart failure, atrioventricular (AV) block without implanted pacemaker, or patients at high risk of complete AV block. Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozide).

Required Medical Information

Documented diagnosis of pseudobulbar affect.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist, Psychiatrist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

NUPLAZID

Affected Drugs

NUPLAZID™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with hepatic impairment.

Required Medical Information

Documented diagnosis of hallucinations and delusions associated with Parkinson's disease psychosis.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist, Psychiatrist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

NURTEC

Affected Drugs

NURTEC®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

For the treatment of migraine, the use of at least one generic triptan therapy (e.g., sumatriptan, zolmitriptan, naratriptan, rizatriptan, etc.) is required prior to initiation of Nurtec unless contraindicated or the member has had an inadequate response to triptan therapy. For the prevention of episodic migraine, the use of at least one standard generic preventative antimigraine therapy (for example, beta blocker (e.g., propranolol, metoprolol, etc.) or antidepressant (e.g., venlafaxine, etc.), or anticonvulsant (e.g., topiramate, divalproex, etc.)) is required prior to initiation of Nurtec unless contraindicated or the member has had an inadequate response

ODOMZO

Affected Drugs

ODOMZO

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A confirmed negative pregnancy test for women of childbearing age prior to initiation of therapy. Confirmed diagnosis of locally advanced basal cell carcinoma (BCC). The documentation of BCC recurrence following surgery or radiation is required if a patient is a candidate for surgery or radiation. Baseline serum creatine kinase (CK) and creatinine levels.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

OFEV

Affected Drugs

OFEV®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Moderate or severe hepatic impairment (Child-Pugh Class B or C).

Required Medical Information

Confirmed diagnosis of 1) idiopathic pulmonary fibrosis (e.g., by high-resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP), etc.) or 2) systemic sclerosis-associated interstitial lung disease (SSc-ILD) or 3) chronic fibrosing interstitial lung diseases with a progressive phenotype. Baseline liver function tests: ALT, AST, bilirubin.

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ONUREG

Affected Drugs

ONUREG®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of acute myeloid leukemia in patients who have achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy. Baseline CBC.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

OPSUMIT

Affected Drugs

OPSUMIT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential.

Required Medical Information

Diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1). Baseline LFTs (AST, ALT, bilirubin) and hemoglobin.

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist, Cardiologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ORENCIA

Affected Drugs

ORENCIA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with biologic DMARDs (e.g., TNF Antagonists)

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Rheumatologist, Hematologist, Transplant specialist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with Rheumatoid Arthritis, Polyarticular-Course Juvenile Rheumatoid Arthritis, or Psoriatic Arthritis, the documented use of at least one conventional Disease-Modifying Anti-Rheumatic Drug (e.g., methotrexate, sulfasalazine, etc.) is required for the current condition prior to the initiation of Orencia. For the indications listed above, the use of at least one prerequisite drug is not required in patients who have already tried a biologic. For prophylaxis of acute graft versus host disease (aGVHD) in patients undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor, Orencia will be used in combination with a calcineurin inhibitor and methotrexate.

ORFADIN

Affected Drugs

ORFADIN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

The diagnosis must be confirmed by laboratory or genetic testing.

Age Restrictions

N/A

Prescriber Restrictions

The prescription is recommended or initially written by gastroenterologist, hematologist, metabolic specialist, nephrologist or other specialist experienced in the treatment of Hereditary Tyrosinemia type 1.

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ORGOVYX

Affected Drugs

ORGOVYX™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of advanced prostate cancer.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Urologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ORKAMBI

Affected Drugs

ORKAMBI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A inducers (e.g., rifampin, etc.). Concomitant use with ivacaftor.

Required Medical Information

A documented diagnosis of cystic fibrosis (CF) in patients who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene confirmed by an FDA-cleared CF mutation test. Baseline liver function tests (AST, ALT, bilirubin).

Age Restrictions

Approve if 1 years old or older.

Prescriber Restrictions

Pulmonologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ORSERDU

Affected Drugs

ORSERDU™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A4 inducers (e.g., rifampin, etc.), moderate CYP3A4 inducers (e.g., efavirenz, etc.), strong CYP3A4 inhibitors (e.g., itraconazole, etc.), or moderate CYP3A4 inhibitors (e.g., fluconazole, etc.). Severe hepatic impairment (Child-Pugh C).

Required Medical Information

Documented diagnosis of ER-positive, 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. Baseline lipid panel.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

OTEZLA

Affected Drugs

OTEZLA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with biologic DMARDs (e.g., TNF Antagonists). Co-administered with strong cytochrome P450 enzyme inducers, such as rifampin, phenobarbital, carbamazepine, phenytoin, etc.

Required Medical Information

N/A

Age Restrictions

Approve if 18 years or older.

Prescriber Restrictions

Rheumatologist, Dermatologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with Psoriatic Arthritis, the documented use of at least one conventional Disease-Modifying Anti-Rheumatic Drug (e.g., methotrexate, sulfasalazine, etc.) is required for the current condition prior to the initiation of Otezla. In patients with plaque psoriasis, the documented use of at least one systemic therapy (e.g., methotrexate, cyclosporine, acitretin, etc.) is required prior to the initiation of Otezla if a patient is a candidate for systemic therapy. For the indications listed above, the use of at least one prerequisite drug is not required in patients who have already tried a biologic.

PEMAZYRE

Affected Drugs

PEMAZYRE™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of 1) 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 (i.e., FoundationOne CDx, etc.) or 2) relapsed or refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor 1 (FGFR1) rearrangement. Baseline phosphate levels and ophthalmologic examination including optical coherence tomography (OCT) prior to initiation of Pemazyre.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

PIQRAY

Affected Drugs

PIQRAY®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Piqray with strong CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, etc.).

Required Medical Information

A documented 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 (e.g., therascreen PIK3CA RGQ PCR Kit, etc.) in combination with fulvestrant in postmenopausal women, or men, following progression on or after an endocrine-based regimen. Baseline fasting plasma glucose levels and HbA1c.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

PIRFENIDONE

Affected Drugs

PIRFENIDONE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Severe hepatic impairment (Child-Pugh Class C). End stage renal disease (ESRD) requiring dialysis.

Required Medical Information

Confirmed diagnosis of idiopathic pulmonary fibrosis (e.g., via high-resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP), etc.). Baseline liver function tests: ALT, AST, bilirubin.

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

PLEGRIDY

Affected Drugs

PLEGRIDY®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

History of hypersensitivity to natural or recombinant interferon beta, peginterferon, or any other component of the formulation.

Required Medical Information

Documented 1) relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and 2) active secondary progressive disease.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

POMALYST

Affected Drugs

POMALYST®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy.

Required Medical Information

A documented diagnosis of multiple myeloma. ANC is greater than or equal to 500 per mcL. Platelet count is greater than or equal to 50,000 per mcL. SrCr is less than or equal to 3.0 mg/dL. Serum bilirubin is less than or equal to 2.0 mg/dL and AST/ALT is less than or equal to 3.0 x ULN. Anti-coagulation prophylaxis is considered in patients with underlying risk factors for deep vein thrombosis or pulmonary embolism. In females of reproductive potential, the use of two reliable methods of contraception is required. A documented diagnosis of AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with multiple myeloma, at least two prior therapies including lenalidomide and bortezomib and demonstration of disease progression on or within 60 days of completion of the last therapy is required prior to initiation of Pomalyst.

POSACONAZOLE

Affected Drugs

POSACONAZOLE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concurrent use of any of the following with posaconazole: sirolimus, pimozide, quinidine, HMG-CoA reductase inhibitors primarily metabolized through CYP3A4 (e.g., atorvastatin, lovastatin, or simvastatin), or ergot alkaloids (e.g., ergotamine or dihydroergotamine)

Required Medical Information

For prevention of invasive Aspergillus and Candida infections, documentation is required that the patients are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Age Restrictions

Approve if 2 years old or older.

Prescriber Restrictions

Infectious Disease Specialist, Oncologist, Transplant Specialist, Hematologist.

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

POSACONAZOLE SUSP

Affected Drugs

POSACONAZOLE SUSP

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concurrent use of any of the following with posaconazole: sirolimus, pimozide, quinidine, HMG-CoA reductase inhibitors primarily metabolized through CYP3A4 (e.g., atorvastatin, lovastatin, or simvastatin), or ergot alkaloids (e.g., ergotamine or dihydroergotamine).

Required Medical Information

For prevention of invasive Aspergillus and Candida infections, documentation is required that the patients are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Age Restrictions

Approve if 13 years old or older.

Prescriber Restrictions

Infectious Disease Specialist, Oncologist, Transplant Specialist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The documented use of itraconazole or fluconazole is required prior to the initiation of posaconazole in patients with refractory oropharyngeal candidiasis.

PREVYMIS

Affected Drugs

PREVYMIS ™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Member is on pimozide or ergot alkaloids. Member is on pitavastatin or simvastatin co-administered with cyclosporine.

Required Medical Information

Documented use for 1) prophylaxis of cytomegalovirus (CMV) infection in CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT) or 2) prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative).

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist, Infection Disease Specialist, Transplant Specialist

Coverage Duration

200 days.

Other Criteria

The documented use of ganciclovir or valacyclovir is required prior to the initiation of Prevymis

PROCRIT

Affected Drugs

PROCRIT®

Covered Uses

All FDA-approved Indications not otherwise excluded from Part D and some other medically accepted indications listed below under Off Label Uses field.

Off-label Uses

Treatment of anemia in low or intermediate-1 risk Myelodysplastic Syndrome patients.

Exclusion Criteria

In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. In patients scheduled for surgery who are willing to donate autologous blood. In patients undergoing cardiac or vascular surgery. As a substitute for RBC transfusions in patients who require immediate correction of anemia. In patients with uncontrolled hypertension. Pure red cell aplasia (PRCA) that occurred after prior treatment with erythropoiesis-stimulating agents (e.g., epoetin alfa, etc.).

Required Medical Information

In patients with CKD, the pretreatment Hgb level is less than 10g/dL or pretreatment Hct is less than 30%. In patients with Non-Myeloid malignancies receiving concomitant myelosuppressive chemotherapy: 1) pretreatment Hgb level is less than 10 g/dL or pretreatment Hct is less than 30% and 2) chemotherapy is planned for a minimum of two additional months. In HIV-infected patients with anemia related to zidovudine-treatment, the pretreatment endogenous serum erythropoietin level is less than 500 milliunits/mL. In patients undergoing elective non-cardiac or non-vascular surgery: 1) DVT prophylaxis is considered and 2) perioperative hemoglobin is greater than 10g/dL and less than or equal to 13g/dL. In patients with low or intermediate-1 risk Myelodysplastic Syndrome: 1) patient must be transfusion-dependent or symptomatic from anemia and 2) pretreatment endogenous serum erythropoietin level is less than 500 milliunits/mL. For all uses: 1) pretreatment serum ferritin is greater than or equal to 100mcg/L or serum transferrin saturation is greater than or equal to 20%, 2) iron, folate, and vitamin B-12 deficiencies have been corrected (if any), and 3) other causes of anemia (e.g., hemolysis, bleeding, etc.) have been ruled out.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

Part B coverage 1) if a prescriber (e.g., nephrologist, nurse practitioner, physician assistant, etc.) receives a monthly capitation payment to manage end-stage renal disease (ESRD) patients' care and 2) if Procrit is furnished to an ESRD patient receiving dialysis services and used for an ESRD-related condition.

PROLASTIN

Affected Drugs

PROLASTIN C®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

IgA deficient patients with antibodies against IgA.

Required Medical Information

Documented alpha1-antitrypsin deficiency with clinically evident emphysema in patients with PiZZ, PiZ(null), Pi(null)(null) or PiSZ genotypes.

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

Prolastin is subject to Part B vs. Part D determination.

PROLIA

Affected Drugs

PROLIA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Hypocalcemia. Patients on Xgeva.

Required Medical Information

Documented history of one of the following: 1. The patient is at high risk for fractures (BMD T score below -2.5, steroids use) or has a history of an osteoporotic fracture. 2. The patient had a fracture and/ or experienced a decrease in BMD T score while on either alendronate, risedronate, ibandronate. 3. The patient is not a candidate for bisphosphonates or intolerant to them.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

Prolia is subject to Part B versus Part D determination.

PROMACTA

Affected Drugs

PROMACTA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

1) A diagnosis of thrombocytopenia in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy or 2) a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP): platelet count is less than 30,000/microliter or less than 50,000/microliter with the risk factors for bleeding and the patient has had an insufficient response to corticosteroids, immunoglobulins, or splenectomy or 3) a diagnosis of severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy or 4) a diagnosis of severe aplastic anemia: Promacta will be used in combination with standard immunosuppressive therapy (e.g. corticosteroids, cyclosporine, etc). Baseline CBC. Baseline liver function tests: ALT, AST, Bilirubin.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

PYRIMETHAMINE

Affected Drugs

PYRIMETHAMINE

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with megaloblastic anemia due to folate deficiency.

Required Medical Information

A documented diagnosis of toxoplasmosis in combination with a sulfonamide.

Age Restrictions

N/A

Prescriber Restrictions

Infectious Disease Specialist

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

For prophylaxis of malaria, the use of at least two other antimalarials (e.g., doxycycline, atovaquone-proguanil, chloroquine phosphate, hydroxychloroquine sulfate, mefloquine, primaquine, etc.) is required prior to the initiation of pyrimethamine. For the treatment of malaria, the use of at least two other antimalarials (e.g., doxycycline, atovaquone-proguanil, chloroquine phosphate, hydroxychloroquine sulfate, mefloquine, primaquine, atovaquone, etc.) is required prior to the initiation of pyrimethamine.

QINLOCK

Affected Drugs

QINLOCK ™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

QUININE SULFATE

Affected Drugs

QUININE SULFATE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients for the treatment of severe or complicated P. falciparum malaria. In patients for prevention of malaria. In patients for the treatment or prevention of nocturnal leg cramps. In patients with any of the following: 1) prolonged QT interval. 2) known hypersensitivity reactions to quinine (e.g., thrombocytopenia, idiopathic thrombocytopenia purpura (ITP) and thrombotic thrombocytopenic purpura (TTP), hemolytic uremic syndrome (HUS), blackwater fever (acute intravascular hemolysis, hemoglobinuria, and hemoglobinemia), etc.) 3) myasthenia gravis 4) optic neuritis.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

7 days

Other Criteria

In patients with Chloroquine-sensitive uncomplicated malaria, the use of chloroquine or hydroxychloroquine is required prior to the use of quinine sulfate unless the use of chloroquine or hydroxychloroquine is contraindicated.

REBIF

Affected Drugs

REBIF®
REBIF REBIDOSE ®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

History of hypersensitivity to natural or recombinant interferon, human albumin, or any other component of the formulation.

Required Medical Information

Documented 1) relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and 2) active secondary progressive disease.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

RELISTOR

Affected Drugs

RELISTOR®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Patients with known or suspected mechanical gastrointestinal obstruction and at increased risk of recurrent obstruction.

Required Medical Information

Documented history of opioid-induced constipation (OIC) in patients with 1) chronic non-cancer pain or 2) advanced illness who are receiving palliative care (e.g., end-stage COPD/emphysema, cardiovascular disease, heart failure, Alzheimer's disease/dementia, HIV/AIDS, incurable cancer or any other advanced illness that requires a palliative opioid therapy).

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The use of at least one formulary laxative (e.g. lactulose, enulose, etc.) for the current condition is required prior to the initiation of Relistor.

RETACRIT

Affected Drugs

RETACRIT®

Covered Uses

All FDA-approved Indications not otherwise excluded from Part D and some other medically accepted indications listed below under Off Label Uses field.

Off-label Uses

Treatment of anemia in low or intermediate-1 risk Myelodysplastic Syndrome patients.

Exclusion Criteria

In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. In patients scheduled for surgery who are willing to donate autologous blood. In patients undergoing cardiac or vascular surgery. As a substitute for RBC transfusions in patients who require immediate correction of anemia. In patients with uncontrolled hypertension. Pure red cell aplasia (PRCA) that occurred after prior treatment with erythropoiesis-stimulating agents (e.g., epoetin alfa, etc.).

Required Medical Information

In patients with CKD, the pretreatment Hgb level is less than 10g/dL or pretreatment Hct is less than 30%. In patients with Non-Myeloid malignancies receiving concomitant myelosuppressive chemotherapy: 1) pretreatment Hgb level is less than 10 g/dL or pretreatment Hct is less than 30% and 2) chemotherapy is planned for a minimum of two additional months. In HIV-infected patients with anemia related to zidovudine-treatment, the pretreatment endogenous serum erythropoietin level is less than 500 milliunits/mL. In patients undergoing elective non-cardiac or non-vascular surgery: 1) DVT prophylaxis is considered and 2) perioperative hemoglobin is greater than 10g/dL and less than or equal to 13g/dL. In patients with low or intermediate-1 risk Myelodysplastic Syndrome: 1) patient must be transfusion-dependent or symptomatic from anemia and 2) pretreatment endogenous serum erythropoietin level is less than 500 milliunits/mL. For all uses: 1) pretreatment serum ferritin is greater than or equal to 100mcg/L or serum transferrin saturation is greater than or equal to 20%, 2) iron, folate, and vitamin B-12 deficiencies have been corrected (if any), and 3) other causes of anemia (e.g., hemolysis, bleeding, etc.) have been ruled out.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

Part B coverage 1) if a prescriber (e.g., nephrologist, nurse practitioner, physician assistant, etc.) receives a monthly capitation payment to manage end-stage renal disease (ESRD) patients' care and 2) if Retacrit is furnished to an ESRD patient receiving dialysis services and used for an ESRD-related condition.

RETEVMO

Affected Drugs

RETEVMO™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A inducers (e.g., rifampin, etc.) or moderate CYP3A inducers (e.g., efavirenz, etc.).

Required Medical Information

Documented diagnosis of 1) 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 or 2) advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, in patients who require systemic therapy or 3) advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, in patients who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate) or 4) locally advanced or metastatic solid tumors with a RET gene fusion in patients who have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

REVLIMID

Affected Drugs

REVLIMID®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential.

Required Medical Information

Revlimid will not be used in patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials. A documented diagnosis of 1) transfusion-dependent anemia due to low-or intermediate-1-risk myelodysplastic syndromes (MDS), where disease is associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities confirmed by testing, 2) multiple myeloma for combination use with dexamethasone, 3) multiple myeloma as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT), 4) mantle cell lymphoma, 5) previously treated follicular lymphoma for combination use with a rituximab product, 6) previously treated marginal zone lymphoma for combination use with a rituximab product.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with mantle cell lymphoma (MCL), documented disease relapse or progression on at least two prior therapies including bortezomib is required prior to the initiation of Revlimid.

REZLIDHIA

Affected Drugs

REZLIDHIA™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A inducers (e.g., rifampin, etc.).

Required Medical Information

Documented susceptible IDH1 mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1, etc.) in adult patients with relapsed or refractory acute myeloid leukemia. Baseline LFTs.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

RINVOQ

Affected Drugs

RINVOQ

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with other JAK inhibitors, or with biologic DMARDs (e.g., TNF Antagonists), or with biologic immunomodulators, or with other biological therapies, or with potent immunosuppressants, such as azathioprine or cyclosporine

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Rheumatologist, Dermatologist, Gastroenterologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with Rheumatoid Arthritis or Psoriatic Arthritis or active Ankylosing Spondylitis, or Non-radiographic Axial Spondyloarthritis, or moderately to severely active Ulcerative Colitis, or moderately to severely active Crohn's disease, the documented use of at least one TNF blocker is required (unless unable to tolerate) prior to initiation of Rinvoq. In patients with refractory, moderate to severe Atopic Dermatitis, the documented use of at least one other systemic drug therapy (e.g., an oral corticosteroid, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, etc.) is required (unless unable to tolerate) prior to initiation of Rinvoq.

ROZLYTREK

Affected Drugs

ROZLYTREK™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of 1) metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive or 2) solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, AND have progressed following treatment or have no satisfactory alternative therapy.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

RUBRACA

Affected Drugs

RUBRACA™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Rubraca will be used 1) as a maintenance treatment in adult patients with deleterious BRCA mutation (germline and/or somatic) associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy or 2) in adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Baseline CBC.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

RYDAPT

Affected Drugs

RYDAPT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Rydapt with strong CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, etc).

Required Medical Information

Documented diagnosis of 1) acute myeloid leukemia (AML) that is FLT3 mutation-positive as detected by an FDA-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay, etc.), 2) aggressive systemic mastocytosis (ASM), 3) systemic mastocytosis with associated hematological neoplasm (SM-AHN), or 4) mast cell leukemia. For AML, Rydapt will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Baseline CBC and platelets.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

SCEMBLIX

Affected Drugs

SCEMBLIX®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Scemblix with itraconazole oral solution containing hydroxypropyl-beta-cyclodextrin.

Required Medical Information

A documented diagnosis of 1) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) in patients previously treated with at least two tyrosine kinase inhibitors (TKIs) or 2) Ph+ CML in CP with the T315I mutation. Baseline CBC, serum lipase and amylase.

Age Restrictions

N/A

Prescriber Restrictions

Hematologist, Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

SECUADO

Affected Drugs

SECUADO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Dementia-related psychosis. Severe hepatic impairment (Child-Pugh C).

Required Medical Information

Documented diagnosis of schizophrenia.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

SIGNIFOR

Affected Drugs

SIGNIFOR®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with hypokalemia, hypomagnesemia, or severe hepatic impairment (Child Pugh C).

Required Medical Information

Adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. A 24-hr urine cortisol to confirm Cushing's disease. Baseline fasting plasma glucose levels, HgA1C, liver function tests, gallbladder ultrasound, electrocardiogram.

Age Restrictions

N/A

Prescriber Restrictions

Endocrinologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

SILDENAFIL CITRATE TABS 20MG

Affected Drugs

SILDENAFIL CITRATE 20MG

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

The concurrent use of nitrates (e.g., nitroglycerin, isosorbide mononitrate or dinitrate, etc.) or guanylate cyclase (GC) stimulators (e.g., riociguat, etc.). The concomitant use of sildenafil citrate with potent CYP 3A inhibitors (e.g., ritonavir, etc). Co-administration of sildenafil citrate with PDE5 inhibitors (e.g., tadalafil, etc).

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

SKYRIZI

Affected Drugs

SKYRIZI™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with biologic DMARDs (e.g., TNF Antagonists)

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Dermatologist, Rheumatologist, Gastroenterologist.

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with plaque psoriasis, the documented use of at least one systemic therapy (e.g., methotrexate, cyclosporine, acitretin, etc.) is required prior to the initiation of Skyrizi if a patient is a candidate for systemic therapy. In patients with Psoriatic Arthritis, the documented use of at least one conventional Disease-Modifying Anti-Rheumatic Drug (e.g., methotrexate, sulfasalazine, etc.) is required prior to the initiation of Skyrizi. In patients with Crohn's disease, the documented use of at least one conventional therapy agent (e.g., 6-mercaptopurine, azathioprine, etc.) is required prior to the initiation of Skyrizi. For the indications listed above, the use of at least one prerequisite drug is not required in patients who have already tried a biologic.

SODIUM OXYBATE

Affected Drugs

SODIUM OXYBATE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients being treated with sedative hypnotic agents (e.g., zolpidem, mirtazapine, etc.) or diagnosis of succinic semialdehyde dehydrogenase deficiency.

Required Medical Information

Documented diagnosis of 1) cataplexy in narcolepsy or 2) excessive daytime sleepiness in narcolepsy.

Age Restrictions

N/A

Prescriber Restrictions

Sleep Specialist or Neurologist

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

A trial of at least one formulary CNS stimulant (e.g., methylphenidate, dextroamphetamine, or modafinil, etc.) is required prior to initiation of sodium oxybate (a trial of a CNS stimulant is not required if a patient with narcolepsy has a history of stimulant drug abuse and dependence or other contraindications to a CNS stimulant).

SOFOSBUVIR-VELPATASVIR

Affected Drugs

SOFOSBUVIR-VELPATASVIR

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of sofosbuvir-velpatasvir with P-gp inducers or moderate to potent CYP inducers (e.g., rifampin, St. John's wort, carbamazepine, etc.).

Required Medical Information

Diagnosis of chronic hepatitis C virus (HCV) genotypes 1a, 1b, 2, 3, 4, 5, or 6 infection confirmed via detectable serum hepatitis C virus RNA by quantitative assay. Criteria will be applied consistent with current AASLD IDSA guidance.

Age Restrictions

N/A

Prescriber Restrictions

Infectious Disease Specialist, Gastroenterologist, Hepatologist

Coverage Duration

The PA will be approved consistent with current AASLD IDSA guidance.

Other Criteria

Criteria will be applied consistent with current AASLD IDSA guidance.

SOMAVERT

Affected Drugs

SOMAVERT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

The patient has had an inadequate response to surgery and/or radiation therapy within the past 6 months if the patient was a candidate for these therapies. The patient is not responsive or intolerant to octreotide or age-adjusted IGF-1 level greater than the upper end of a normal range.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

SORAFENIB

Affected Drugs

SORAFENIB

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concurrent use with carboplatin and paclitaxel in patients with squamous cell lung cancer.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

SPRYCEL

Affected Drugs

SPRYCEL®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Sprycel will be used in patients with 1) newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, 2) chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib, or 3) Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy (e.g. imatinib, etc.). In pediatric patients with Ph+ CML in chronic phase or newly diagnosed Ph+ ALL in combination with chemotherapy.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

STELARA

Affected Drugs

STELARA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with biologic DMARDs (e.g., TNF Antagonists)

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Rheumatologist, Dermatologist, Gastroenterologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with Psoriatic Arthritis, the documented use of at least one conventional Disease-Modifying Anti-Rheumatic Drug (e.g., methotrexate, sulfasalazine, etc.) is required for the current condition prior to the initiation of Stelara. In patients with plaque psoriasis, the documented use of at least one systemic therapy (e.g., methotrexate, cyclosporine, acitretin, etc.) is required prior to the initiation of Stelara if a patient is a candidate for systemic therapy. In patients with Crohn's disease, the documented use of at least one conventional therapy agent (e.g., 6-mercaptopurine, azathioprine, etc.) is required prior to the initiation of Stelara. For the indications listed above, the use of at least one prerequisite drug is not required in patients who have already tried a biologic.

STIVARGA

Affected Drugs

STIVARGA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with severe hepatic impairment (Child-Pugh Class C)

Required Medical Information

Baseline liver function test (ALT, AST and bilirubin) prior to initiation of Stivarga. Documentation of adequately-controlled blood pressure prior to initiation of Stivarga.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with metastatic colorectal cancer, a documented use of fluoropyrimidine-oxaliplatin-irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy is required prior to initiation of Stivarga. In patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST), a documented use of imatinib and sunitinib is required prior to initiation of Stivarga. In patients with hepatocellular carcinoma, a documented use of sorafenib is required prior to initiation of Stivarga.

SUNITINIB

Affected Drugs

SUNITINIB

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of 1) gastrointestinal stromal tumor (GIST) or 2) advanced renal cell carcinoma (RCC) or 3) recurrent RCC following nephrectomy as adjuvant treatment or 4) progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in adult patients with unresectable locally advanced or metastatic disease.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with gastrointestinal stromal tumors (GIST), the documented use of imatinib is required prior to the initiation of sunitinib.

SYNRIBO

Affected Drugs

SYNRIBO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with poorly controlled diabetes mellitus.

Required Medical Information

A documented diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML). ANC is greater than or equal to 1.0 x 10(9)/L. Platelet Count is greater than or equal to 50 x 10(9)/L.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

A documented resistance and/or intolerance to at least two tyrosine kinase inhibitors (e.g., imatinib, dasatinib, nilotinib, bosutinib, etc.) is required prior to initiation of Synribo.

TABRECTA

Affected Drugs

TABRECTA™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A inducers (e.g., rifampicin, etc.) or moderate CYP3A inducers (e.g., efavirenz, etc.).

Required Medical Information

Documented 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 (e.g., FoundationOne CDx, etc.). Baseline LFTs.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TADALAFIL

Affected Drugs

ALYQ

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

The concurrent use of nitrates (e.g., nitroglycerin, isosorbide mononitrate or dinitrate, etc.) or guanylate cyclase (GC) stimulators (e.g., riociguat etc.) or potent CYP 3A inhibitors (e.g., ketoconazole, itraconazole, etc.) or PDE5 inhibitors (e.g., tadalafil, sildenafil, etc) or potent inducers of CYP3A (e.g., rifampin).

Required Medical Information

Documentation of pulmonary arterial hypertension (PAH) (WHO Group 1)

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist, Cardiologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TAFINLAR

Affected Drugs

TAFINLAR®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with colorectal cancer or in patients with wild-type BRAF solid tumors.

Required Medical Information

A documented diagnosis of unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test when Tafinlar will be used as a single agent. A documented diagnosis of (1) unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, when Tafinlar will be used in combination with Mekinist, (2) metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test (e.g., Oncomine Dx Target Test, etc.), (3) locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options, (4) adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test and involvement of lymph node(s) following complete resection, (5) unresectable or metastatic solid tumors with BRAF V600E mutation in patients who have progressed following prior treatment and have no satisfactory alternative treatment options, or (6) low-grade glioma (LGG) with a BRAF V600E mutation requiring systemic therapy. In patients with NSCLC, or ATC, or unresectable or metastatic solid tumors, or as adjuvant treatment in patients with melanoma, or LGG, Taflinlar will be used in combination with trametinib (Mekinist). Baseline dermatologic evaluation.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TAGRISSO

Affected Drugs

TAGRISSO™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of (1) metastatic 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 (e.g., cobas EGFR Mutation Test v2, FoundationOne CDx, etc.), or (2) NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test (e.g., cobas EGFR Mutation Test v2, FoundationOne CDx, etc.) in patients after tumor resection as adjuvant therapy or (3) metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC, as detected by an FDA-approved test (e.g., the cobas EGFR Mutation Test v2, etc.). Baseline ECG and electrolytes in patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval. Baseline left ventricular ejection fraction (LVEF) measurement obtained via ECHO or MUGA.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

Documented disease progression following treatment with at least one prior EGFR tyrosine kinase inhibitor (TKI) therapy (e.g., afatinib, erlotinib, etc.) is required prior to

the initiation of Tagrisso in patients with metastatic EGFR T790M mutation-positive NSCLC.

TALZENNA

Affected Drugs

TALZENNA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Exclusion Criteria

N/A

Off-label Uses

N/A

Required Medical Information

Documented diagnosis of 1) deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer, as detected by an FDA approved test (e.g., BRACAnalysis CDx, etc.). For gBRCAm HER2-negative locally advanced or metastatic breast cancer, Talzenna will be used as a single agent OR 2) homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC). For HRR gene-mutated mCRPC, Talzenna will be used: a) in combination with enzalutamide AND b) concurrently with a gonadotropin-releasing hormone (GnRH) analog unless the patient has had a bilateral orchiectomy.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Urologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TASIGNA

Affected Drugs

TASIGNA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

The patient's QTc interval 480 msec or greater. The patient's baseline potassium and magnesium levels are not within normal limits. Concurrent use of strong CYP3A4 Inhibitors or drugs that prolong QT interval.

Required Medical Information

Documented Philadelphia chromosome positive status is required for chronic myeloid leukemia (Ph+ CML). In adult patients, the documented history of resistance to imatinib that is defined as one of the following: failure to achieve a complete hematologic response by 3 months, failure to achieve a cytogenic response by 6 months or major cytogenic response by 12 months, progression of disease after a previous cytogenic or hematologic response (the documented history of resistance to imatinib is not needed if the patient is intolerant to imatinib or in newly-diagnosed patients with Ph+ CML in chronic phase). In pediatric patients, the documented history of resistance or intolerance to at least one prior tyrosine-kinase inhibitor therapy (the documented history of resistance to at least one prior tyrosine-kinase inhibitor therapy is not needed in newly-diagnosed patients with Ph+ CML in chronic phase). Baseline ECG. Baseline Potassium and Magnesium levels.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TASIMELTEON

Affected Drugs

TASIMELTEON

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Severe hepatic impairment (Child-Pugh Class C). Co-administration of tasimelteon with strong CYP1A2 inhibitors (e.g., fluvoxamine, etc.) or strong CYP3A4 inducers (e.g., rifampin, etc.).

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Sleep Specialist or Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TAZVERIK

Affected Drugs

TAZVERIK™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of 1) metastatic or locally advanced epithelioid sarcoma not eligible for complete resection or 2) relapsed or refractory follicular lymphoma in patients whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test (e.g., cobas EZH2 Mutation Test, etc.) and who have received at least 2 prior systemic therapies or 3) relapsed or refractory follicular lymphoma in patients who have no satisfactory alternative treatment options. Baseline CBC.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist.

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TEPMETKO

Affected Drugs

TEPMETKO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with diagnosis of interstitial lung disease (ILD) or pneumonitis. Concomitant use with dual strong CYP3A inhibitors and P-gp inhibitors OR with strong CYP3A inducers.

Required Medical Information

Documented diagnosis of metastatic non-small cell lung cancer (NSCLC) harboring mesenchymalepithelial transition (MET) exon 14 skipping alteration. Baseline LFTs.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TERIFLUNOMIDE

Affected Drugs

TERIFLUNOMIDE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with severe hepatic impairment. Pregnancy in females of reproductive potential. Concurrent use of leflunomide. In patients with active or chronic infection (e.g., pneumonia, aspergillosis, tuberculosis, etc.).

Required Medical Information

Documented diagnosis of relapsing forms of multiple sclerosis to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease. Recent (e.g., within six months) complete blood count (CBC). Serum ALT less than or equal to 2 times ULN is required prior to the initiation of teriflunomide.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TERIPARATIDE

Affected Drugs

TERIPARATIDE

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Patients have increased baseline risk for osteosarcoma (e.g., those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton)

Required Medical Information

Documented history of one of the following: 1. The patient is at high risk for fractures (BMD T score below -2.5, steroids use) or has a history of an osteoporotic fracture. 2. The patient had a fracture and/ or experienced a decrease in BMD T score while on either alendronate, risedronate, and ibandronate. 3. The patient is not a candidate for bisphosphonates or intolerant to them.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for 2 years.

Other Criteria

N/A

TETRABENAZINE

Affected Drugs

TETRABENAZINE

Covered Uses

All FDA-approved Indications not otherwise excluded from Part D and some other medically accepted indications listed below under Off Label Uses field.

Off-label Uses

Treatment of Tardive dyskinesia, Gilles de la Tourette's syndrome

Exclusion Criteria

Actively suicidal patients, or patients with untreated or inadequately treated depression. Impaired hepatic function. Concurrent use of monoamine oxidase inhibitors, reserpine or deutetrabenazine.

Required Medical Information

Documented diagnosis of Huntington's disease chorea, Tardive dyskinesia, or Gilles de la Tourette's syndrome.

Age Restrictions

N/A

Prescriber Restrictions

Neurologist, Psychiatrist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

THALOMID

Affected Drugs

THALOMID®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

In patients with Multiple Myeloma, the concurrent use of Thalomid with dexamethasone.

Age Restrictions

N/A

Prescriber Restrictions

The prescription must be initially written or recommended by the Oncologist, Hematologist, Dermatologist, or Infection Disease Specialist.

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

Thalomid must be prescribed by a physician registered with System for Thalomid Education and Prescribing Safety Program.

TIBSOVO

Affected Drugs

TIBSOVO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Tibsovo with strong CYP3A inducers (e.g., rifampin, etc.). Diagnosis of Guillain-Barre syndrome.

Required Medical Information

Documented susceptible IDH1 mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1, etc.) in adult patients with 1) newly-diagnosed AML who are greater than or equal 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy or 2) relapsed or refractory AML or 3) locally advanced or metastatic cholangiocarcinoma who have been previously treated.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TRACLEER

Affected Drugs

TRACLEER®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential.

Required Medical Information

Diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) in patients with NYHA Functional Class II-IV symptoms. Baseline LFTs (ALT, AST, bilirubin).

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist, Cardiologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The prior use of sildenafil citrate is required for the current condition in adult patients initiating Tracleer.

TRELSTAR

Affected Drugs

TRELSTAR®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients who are or may become pregnant.

Required Medical Information

Documented diagnosis of advanced prostate cancer. Baseline electrolytes (e.g., potassium, magnesium, etc.), serum testosterone and ECG.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TRETINOIN TOPICAL

Affected Drugs

TRETINOIN

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Cosmetic use.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

N/A

TRIKAFTA

Affected Drugs

TRIKAFTA™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

A documented diagnosis of cystic fibrosis (CF) with at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

Age Restrictions

Approve if 2 years old or older.

Prescriber Restrictions

Pulmonologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TUKYSA

Affected Drugs

TUKYSA™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, etc.) or moderate CYP2C8 inducers (e.g. rifampin, etc.).

Required Medical Information

In combination with trastuzumab or capecitabine for a documented diagnosis of advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received at least one prior anti-HER2-based regimens in the metastatic setting OR 2) In combination with trastuzumab for a documented diagnosis of RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist, Gastroenterologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TURALIO

Affected Drugs

TURALIO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery. Baseline LFT (e.g., ALT, AST, bilirubin, etc.).

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

TYMLOS

Affected Drugs

TYMLOS™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Patients that have an increased baseline risk for osteosarcoma (e.g., those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton), or underlying hypercalcemic disorder (e.g., primary hyperparathyroidism). Use of Tymlos and parathyroid hormone analogs (e.g. Forteo, etc.) for more than 2 years.

Required Medical Information

Documented history of one of the following: 1. The patient is at high risk for fractures (BMD T score below -2.5, steroids use) or has a history of an osteoporotic fracture. 2. The patient had a fracture and/ or experienced a decrease in BMD T score while on either alendronate, risedronate, and ibandronate. 3. The patient is not a candidate for bisphosphonates or intolerant to them.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for 2 years.

Other Criteria

N/A

UBRELVY

Affected Drugs

UBREVELY®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The use of at least one generic triptan therapy (e.g., sumatriptan, zolmitriptan, naratriptan, rizatriptan, etc.) is required prior to initiation of Ubrelvy unless contraindicated or the member has had an inadequate response to triptan therapy.

UDENYCA

Affected Drugs

UDENYCA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Baseline CBC and platelet count.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist or Infectious Disease Specialist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

UPTRAVI

Affected Drugs

UPTRAVI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Severe hepatic impairment (Child-Pugh Class C).

Required Medical Information

Diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1).

Age Restrictions

N/A

Prescriber Restrictions

Pulmonologist, Cardiologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

VALCHLOR

Affected Drugs

VALCHLOR®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

At least one prior skin-directed therapy (e.g., bexarotene, methotrexate, etc.) is required for the treatment of the current condition prior to initiation of Valchlor.

VASCEPA

Affected Drugs

VASCEPA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with hypertriglyceridemia, a documented use of omega-3 acid ethyl esters is required prior to initiation of Vascepa (a prior use of omega-3 acid ethyl esters is not required if Vascepa is used for cardiovascular event risk reduction in patients on statin therapy with established cardiovascular disease or with type 2 diabetes and additional risk factors for cardiovascular disease).

VELTASSA

Affected Drugs

VELTASSA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders.

Required Medical Information

Baseline serum magnesium.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

VENCLEXTA

Affected Drugs

VENCLEXTA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with strong CYP3A4 inhibitors (e.g., ketoconazole, conivaptan, clarithromycin, indinavir, itraconazole, lopinavir, ritonavir, telaprevir, posaconazole, voriconazole, etc.) at initiation and during ramp-up phase.

Required Medical Information

A documented diagnosis of 1) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) or 2) in combination with azacitidine or decitabine or low-dose cytarabine, 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.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

VERZENIO

Affected Drugs

VERZENIO™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of Verzenio with strong CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, etc.) or ketoconazole.

Required Medical Information

Documented diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence: Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment or documented diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer: Verzenio will be used (1) in combination with fulvestrant in adults with disease progression following endocrine therapy OR (2) as monotherapy in adults with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting OR (3) in combination with an aromatase inhibitor as initial endocrine-based therapy in adults. Baseline LFTs, CBC.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

VITRAKVI

Affected Drugs

VITRAKVI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with sensitive CYP3A4 substrates (e.g., midazolam, triazolam, etc.).

Required Medical Information

Documented diagnosis of solid tumor that 1) have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, 2) are metastatic or where surgical resection is likely to result in severe morbidity, AND 3) have no satisfactory alternative treatments or that have progressed following treatment.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

VIZIMPRO

Affected Drugs

VIZIMPRO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Interstitial Lung Disease

Required Medical Information

Documented diagnosis of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test (e.g., cobas EGFR Mutation Test v2, FoundationOne CDx, etc.).

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

VONJO

Affected Drugs

VONJO™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of strong CYP3A4 inhibitors (i.e., clarithromycin, etc.) or inducers (i.e., rifampin, etc.). Active bleeding. Baseline QTc greater than 480 msec. Baseline eGFR less than 30mL/min. Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment.

Required Medical Information

A documented diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 109/L. Baseline CBC and QTc.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

VORICONAZOLE INJ

Affected Drugs

VORICONAZOLE INJECTION

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for 6 months.

Other Criteria

The requested drug will be used intravenously.

VOSEVI

Affected Drugs

VOSEVI®

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use of rifampin, amiodarone, P-gp inducers, or moderate to potent CYP2B6, CYP2C8, or CYP3A4 inducers (e.g., carbamazepine).

Required Medical Information

Documented diagnosis of chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) with: 1) genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor (e.g., Harvoni, Epclusa, ledipasvir-sofosbuvir, sofosbuvir-velpatasvir, etc.) or 2) genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. Criteria will be applied consistent with current AASLD IDSA guidance.

Age Restrictions

N/A

Prescriber Restrictions

Infectious Disease Specialist, Gastroenterologist, Hepatologist

Coverage Duration

The PA will be approved consistent with current AASLD IDSA guidance.

Other Criteria

Criteria will be applied consistent with current AASLD IDSA guidance

VOTRIENT

Affected Drugs

VOTRIENT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pre-existing severe hepatic impairment (total bilirubin greater than 3 times upper limit of normal). Patients who were hospitalized for cerebral hemorrhage, or clinically significant GI hemorrhage in the past 6 months.

Required Medical Information

Baseline serum liver tests: AST, ALT, bilirubin, EKG, electrolytes (e.g., calcium, magnesium, potassium), thyroid function tests, urinalysis.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

VUMERITY

Affected Drugs

VUMERITY™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented 1) relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and 2) active secondary progressive disease. Recent (e.g., within six months) complete blood count (CBC).

Age Restrictions

N/A

Prescriber Restrictions

Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

WELIREG

Affected Drugs

WELIREG™

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of von Hippel-Lindau (VHL) disease in patients who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Endocrinologist, Neurologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

XALKORI

Affected Drugs

XALKORI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with congenital long QT syndrome. In a patient restarting Xalkori, the patient has experienced 1) QTc greater than 500 ms or greater than or equal to 60 ms change from baseline with Torsade de pointes or polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia and 2) ALT or AST elevation greater than 3 times ULN with concurrent total bilirubin elevation greater than 1.5 times ULN (in the absence of cholestasis or hemolysis) and 3) any Grade drug-related interstitial lung disease/pneumonitis with the previous Xalkori treatment.

Required Medical Information

The diagnosis of 1) Anaplastic Lymphoma Kinase (ALK)-positive or ROS1-positive metastatic Non-Small Cell Lung Cancer (NSCLC) detected by an FDA approved test, 2) Anaplastic Lymphoma Kinase (ALK)-positive relapsed or refractory systemic anaplastic large cell lymphoma (ALCL), or 3) ALK-positive unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT). Baseline CBC with differential and liver function tests including ALT and total bilirubin.

Age Restrictions

ALCL: Approve if 1 year of age and older and young adults (e.g., 1 to 21 y.o.). IMT: Approve if 1 year of age and older. All others: none

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

XELJANZ

Affected Drugs

XELJANZ®
XELJANZ® XR

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with biologic DMARDs (e.g., TNF Antagonists) or with potent immunosuppressants, such as azathioprine or cyclosporine.

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Rheumatologist, Gastroenterologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with Rheumatoid Arthritis, active Polyarticular Course Juvenile Idiopathic Arthritis, Psoriatic Arthritis, moderately to severely active ulcerative colitis, or Ankylosing Spondylitis, the documented use of at least one TNF blocker is required (unless unable to tolerate) prior to initiation of Xeljanz.

XERMELO

Affected Drugs

XERMELO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of carcinoid syndrome diarrhea in patients inadequately controlled by somatostatin analog (SSA) therapy. Xermelo will be used in combination with SSA therapy.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

N/A

XGEVA

Affected Drugs

XGEVA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients with pre-existing hypocalcemia

Required Medical Information

1) Giant cell tumor of bone: a diagnosis of unresectable giant cell tumor of bone or where surgical resection is likely to result in severe morbidity, or 2) prevention of skeletal related events in patients with multiple myeloma or bone metastases from solid tumors: diagnosis of a) multiple myeloma or b) solid tumors and evidence of one or more metastatic bone lesions, or 3) hypercalcemia of malignancy: persistent hypercalcemia refractory to bisphosphonate therapy..

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

Xgeva is not used in patients on Prolia.

XIFAXAN

Affected Drugs

XIFAXAN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of 1) travelers diarrhea caused by Escherichia coli, 2) hepatic encephalopathy, or 3) irritable bowel syndrome with diarrhea (IBS-D).

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with travelers diarrhea, a documented use of ciprofloxacin, levofloxacin, or azithromycin is required prior to initiation of Xifaxan. In patients with hepatic encephalopathy, a documented use of lactulose is required prior to initiation of Xifaxan. In patients with IBS-D, a documented use of loperamide is required prior to initiation of Xifaxan.

XOLAIR

Affected Drugs

XOLAIR®

Covered Uses

All Medically-accepted Indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

In patients with moderate to severe persistent asthma 1) a positive skin test or in vitro reactivity to a perennial aeroallergen (e.g., house dust mite, animal dander, mold spores, etc.) and 2) baseline serum IgE greater than or equal to 30 IU/mL. In patients with seasonal or perennial allergic rhinitis, a positive skin test or in vitro for one or more relevant allergens (e.g., grass, tree, or weed pollen, mold spores, house dust mite, etc.).

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with moderate to severe persistent asthma, the use of at least one formulary inhaled corticosteroid (e.g., fluticasone-salmeterol diskus, mometasone-formoterol, etc.) is required prior to the initiation of Xolair. In patients with chronic idiopathic urticaria, seasonal allergic rhinitis, or perennial allergic rhinitis, the use of at least one formulary H1 antihistamine (e.g., levocetirizine, desloratadine, etc.) is required prior to the initiation of Xolair. In patients with nasal polyps, the use of at least one formulary nasal corticosteroid (e.g., mometasone, etc.) is required prior to the initiation of Xolair. In patients with immunotherapy-related toxicities, the use of at least one conventional therapy (e.g., levocetirizine, desloratadine, prednisone, methylprednisolone etc.) or aprepitant is required prior to the initiation of Xolair. In

patients with systemic mastocytosis, the use of at least one conventional therapy (e.g., levocetirizine, desloratadine, prednisone, etc.) is required prior to the initiation of Xolair.

XOSPATA

Affected Drugs

XOSPATA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Concomitant use with P-gp and strong CYP3A inducers (e.g., phenytoin, rifampin, carbamazepine, etc.), or strong CYP3A inhibitors (e.g., ketoconazole, clarithromycin, voriconazole, etc.). Patients with prolonged QT interval (e.g., QTcF greater than 500 msec, etc.).

Required Medical Information

Documented diagnosis of e relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay, etc.). Baseline potassium and magnesium.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

XPOVIO

Affected Drugs

XPOVIO

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Documented diagnosis of 1) multiple myeloma, Xpovio will be used in combination with dexamethasone and bortezomib, after receiving at least one prior therapy or 2) relapsed or refractory multiple myeloma, Xpovio will be used in combination with dexamethasone or 3) relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after receiving at least two prior lines of systemic therapy. Baseline neutrophil count and sodium level.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

XTANDI

Affected Drugs

XTANDI®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In women who are or may become pregnant

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Urologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

XYREM

Affected Drugs

XYREM®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients being treated with sedative hypnotic agents (e.g., zolpidem, mirtazapine, etc.) or diagnosis of succinic semialdehyde dehydrogenase deficiency.

Required Medical Information

Documented diagnosis of 1) cataplexy in narcolepsy or 2) excessive daytime sleepiness in narcolepsy.

Age Restrictions

N/A

Prescriber Restrictions

Sleep Specialist or Neurologist

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

A trial of one formulary CNS stimulant (e.g., methylphenidate, dextroamphetaminemodafinil, etc.) is required prior to initiation of Xyrem (a trial of a CNS stimulant is not required if a patient with narcolepsy has a history of stimulant drug abuse and dependence or other contraindications to a CNS stimulant).

XYWAV

Affected Drugs

XYWAV®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

In patients being treated with sedative hypnotic agents (e.g., zolpidem, mirtazapine, etc.) or diagnosis of succinic semialdehyde dehydrogenase deficiency.

Required Medical Information

Documented diagnosis of 1) cataplexy in narcolepsy or 2) excessive daytime sleepiness in narcolepsy or 3) idiopathic hypersomnia.

Age Restrictions

N/A

Prescriber Restrictions

Sleep Specialist or Neurologist

Coverage Duration

The PA will be approved through the remainder of the contract year.

Other Criteria

In patients with narcolepsy, a trial of one formulary CNS stimulant (e.g., methylphenidate, dextroamphetamine, modafinil, etc.) is required prior to initiation of Xywav (a trial of a CNS stimulant is not required if a patient with narcolepsy has a history of stimulant drug abuse and dependence or other contraindications to a CNS stimulant).

YONSA

Affected Drugs

YONSA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential. Severe hepatic impairment (Child-Pugh Class C). NYHA Class III or IV heart failure. LVEF is less than 50%.

Required Medical Information

Yonsa is administered in combination with methylprednisolone. AST and ALT less than or equal to 2.5X ULN and total bilirubin less than or equal to 1.5X ULN. Serum potassium is within normal limits prior to initiation.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ZARXIO

Affected Drugs

ZARXIO®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

Baseline complete blood count (CBC) and platelet count.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist, or Infectious disease specialist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ZEJULA

Affected Drugs

ZEJULA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Pregnancy in females of reproductive potential. Zejula will not be initiated until patients have recovered from hematological toxicity caused by previous chemotherapy (less than or equal Grade 1).

Required Medical Information

Documented diagnosis of 1) deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in a complete or partial response to platinum-based chemotherapy or 2) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy. Baseline CBC.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Gynecologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ZELBORAF

Affected Drugs

ZELBORAF®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

Wild-type BRAF melanoma. Uncorrectable electrolyte abnormalities and long QT syndrome.

Required Medical Information

The diagnosis of 1) unresectable or metastatic melanoma with BRAFV600E mutation confirmed by an FDA-approved test (e.g., cobas 4800 BRAF V600 Mutation Test, etc.) or 2) Erdheim-Chester Disease with BRAF V600 mutation. In patients who are taking medications known to prolong the QT interval, discontinuation of these medications is required with initiation of Zelboraf. Baseline ECG and electrolytes, including potassium, magnesium, and calcium, dermatologic evaluation, liver enzymes (transaminases and alkaline phosphatase) and bilirubin. QTc interval is less than or equal to 500ms. In a patient restarting Zelboraf, the patient hasn't experienced Common Terminology Criteria for Adverse Events v4.0 (CTC-AE) Grade 2 (Intolerable) or Grade 3: 3rd appearance and Grade 4: 2nd appearance with the previous Zelboraf treatment.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A

ZOLINZA

Affected Drugs

ZOLINZA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

N/A

Prescriber Restrictions

The prescription must be initially written or recommended by the Oncologist.

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

The documented use of at least one systemic therapies for the current condition: bexarotene oral or CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or interferon alfa-2b or methotrexate is required prior to the initiation of Zolinza.

ZYDELIG

Affected Drugs

ZYDELIG®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

History of serious allergic reactions, including anaphylaxis and toxic epidermal necrolysis. In patients with life-threatening diarrhea, intestinal perforation, or symptomatic pneumonitis.

Required Medical Information

CBC and liver function tests: ALT, AST, bilirubin.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist, Hematologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

In patients with relapsed chronic lymphocytic leukemia (CLL), Zydelig is used in combination with rituximab (for whom rituximab alone would be considered appropriate therapy due to other co-morbidities).

ZYKADIA

Affected Drugs

ZYKADIA®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D.

Off-label Uses

N/A

Exclusion Criteria

N/A

Required Medical Information

The diagnosis of Anaplastic Lymphoma Kinase (ALK)-positive metastatic Non-Small Cell Lung Cancer. Baseline ECG and liver function tests including ALT and total bilirubin. In a patient restarting Zykadia, the patient hasn't experienced 1) ALT or AST elevation greater than 3 times ULN with concurrent total bilirubin elevation greater than 2 times ULN (in the absence of cholestasis or hemolysis) and 2) any Grade treatment-related interstitial lung disease/pneumonitis and 3) QTc interval prolongation with Torsade de pointes or polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia and 4) life-threatening bradycardia if no contributing concomitant medication with the previous Zykadia treatment.

Age Restrictions

N/A

Prescriber Restrictions

Oncologist

Coverage Duration

The PA will be approved for lifetime.

Other Criteria

N/A