

## 2024 Prior Authorization Criteria

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## **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.

## **AKEEGA**

### **Affected Drugs**

AKEEGA™

### **Covered Uses**

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

### **Off-label Uses**

N/A

### **Exclusion Criteria**

Myelodysplastic Syndrome. Acute Myeloid Leukemia. Posterior Reversible Encephalopathy Syndrome. Concomitant use with strong CYP3A4 inducers (e.g., rifampin, etc.). Moderate or Severe Hepatic impairment.

### **Required Medical Information**

Documented diagnosis of deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer, used in combination with prednisone. Baseline CBC.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist, Urologist

### **Coverage Duration**

The PA will be approved for lifetime.

### **Other Criteria**

N/A



## **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., dicyclomine, 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



# **AUGTYRO**

## **Affected Drugs**

AUGTYRO™

## **Covered Uses**

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

## **Off-label Uses**

N/A

## **Exclusion Criteria**

Interstitial Lung Disease (ILD) or Pneumonitis. Concomitant use with strong and moderate CYP3A inhibitors (e.g., itraconazole, etc.), p-gp inhibitors (e.g., itraconazole, etc.), strong and moderate CYP3A inducers (e.g., rifampin, etc.).

## **Required Medical Information**

Documented diagnosis of locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC). Baseline LFTs, serum CPK, serum uric acid levels

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

Oncologist, Pulmonologist

## **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 CYP3A4 inducers (e.g., phenytoin, rifampin, carbamazepine, etc.).

### **Required Medical Information**

Documented diagnosis of locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 genetic alterations and disease has progressed on or after at least one line of prior systemic therapy.

### **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®  
ENVARUS 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 or resistant or intolerant to prior therapy chronic phase Ph+ chronic myelogenous leukemia (CML) or 2) 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 theascreen BRAF V600E RGQ PCR Kit, etc.) after prior therapy (e.g., irinotecan, etc.), in combination with cetuximab or 3) metastatic non-small cell lung cancer with a BRAF V600E mutation, as detected by an FDA-approved test, in combination with binimetinib. 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**

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

### **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 6 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 patient's 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  $50 \times 10^9/L$ . 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. Baseline blood eosinophil level greater than or equal to 150 cells per microliter or 3) chronic rhinosinusitis with nasal polyposis as add-on maintenance treatment or 4) eosinophilic esophagitis (EoE) in patients weighing at least 15kg 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 use of at least one medium or high potency topical corticosteroid (e.g., fluocinonide, etc.) or one topical calcineurin inhibitor (e.g., tacrolimus) is required (unless contraindicated or unable to tolerate) prior to initiation of Dupixent. In patients with moderate-to-severe eosinophilic asthma, the patient has been unable to achieve adequate asthma control while on inhaled corticosteroid therapy (unless contraindicated or unable to tolerate). In patients with chronic rhinosinusitis with nasal polyposis, the patient is not adequately controlled on at least one formulary nasal corticosteroid (e.g., mometasone, etc.) unless



contraindicated or unable to tolerate. In patients with EoE, the 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. In patients with prurigo nodularis, the use of at least one prerequisite drug is not required 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 prostate 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

## **EMGALITY**

### **Affected Drugs**

EMGALITY®

### **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 preventive treatment of migraine, 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 Emgality unless contraindicated or the member has had an inadequate response. For the treatment of episodic cluster headache, the use of at least one prerequisite drug is not required.

## **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.

## **ENDARI**

### **Affected Drugs**

ENDARI™

### **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 complications of sickle cell disease.

### **Age Restrictions**

Approve if 5 years old or older

### **Prescriber Restrictions**

Hematologist

### **Coverage Duration**

The PA will be approved for lifetime.

### **Other Criteria**

N/A

## **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 pancreatic 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

## **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 exemestane 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

## **FRUZAQLA**

### **Affected Drugs**

FRUZAQLA™

### **Covered Uses**

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

### **Off-label Uses**

N/A

### **Exclusion Criteria**

Gastrointestinal perforation or fistula. Posterior Reversible Encephalopathy Syndrome. Arterial thromboembolism. Concomitant use with strong CYP3A inducers (e.g., rifampin, etc.).

### **Required Medical Information**

Documented diagnosis of metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy. Baseline LFTs, urine protein.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist, Gastroenterologist

### **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 failure 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

## **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 theascreen 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.

## **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 failure 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**

Concomitant use with strong CYP3A inducers (e.g. phenytoin, rifampin, carbamazepine, enzalutamide, etc.). Interstitial Lung Disease (ILD) or Pneumonitis.

### **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).

## **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, Dermatologist, or Hematologist

### **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.

### **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

## **ISTURISA**

### **Affected Drugs**

ISTURISA®

### **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: Diagnosis of Cushing's disease. Documentation that pituitary surgery is not an option or has not been curative. Reauthorization: Documentation of positive clinical response to therapy (e.g., clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in disease symptoms).

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Endocrinologist

### **Coverage Duration**

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

### **Other Criteria**

N/A

## **IWILFIN**

### **Affected Drugs**

IWILFIN™

### **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 high-risk neuroblastoma (HRNB) with at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy. Baseline CBC, LFTs.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist, Neurologist

### **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  $50 \times 10^9/L$ .

### **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 1) relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a BTK inhibitor or 2) chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 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

## **KOSELUGO**

### **Affected Drugs**

KOSELUGO®

### **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 neurofibromatosis type 1 with symptomatic, inoperable plexiform neurofibromas.

### **Age Restrictions**

Approve if 2 years old and up to 18 years old.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

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

### **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., theascreen 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., theascreen 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 unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test when Mekinist will be used as a single agent. 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 1) 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 or 2) metastatic non-small cell lung cancer with a BRAF V600E mutation, as detected by an FDA-approved test, 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

## **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/mm<sup>3</sup>. Baseline platelet count is equal to or greater than 75,000/mm<sup>3</sup>.

### **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

## **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



## **OJJAARA**

### **Affected Drugs**

OJJAARA

### **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 or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) or post-essential thrombocythemia (ET)], in adults with anemia. Baseline CBC, 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**

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, or Oncologist

### **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.

## **PAZOPANIB**

### **Affected Drugs**

PAZOPANIB

### **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**

Documented diagnosis of 1) advanced renal cell carcinoma or 2) advanced soft tissue sarcoma after prior chemotherapy. 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

## **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., theascreen PIK3CA RGQ PCR Kit, etc.) in combination with fulvestrant in adults, 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 mL. Platelet count is greater than or equal to 50,000 per mL. 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.

## **PREVMIS**

### **Affected Drugs**

PREVMIS™

### **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 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**

The PA will be approved for 200 days.

### **Other Criteria**

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

## **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**

N/A



## **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.

## **QULIPTA**

### **Affected Drugs**

QULIPTA

### **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 Qulipta unless contraindicated or the member has had an inadequate response.

## **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



## **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.

## **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, Tafinlar 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

# **TAGRISO**

## **Affected Drugs**

TAGRISO™

## **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.), or (4) locally advanced or metastatic NSCLC whose tumors have 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 combination with pemetrexed and platinum-based chemotherapy. 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 cytogenetic response by 6 months or major cytogenetic response by 12 months, progression of disease after a previous cytogenetic 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) relapsed or refractory myelodysplastic syndromes or 4) 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

## **TRUQAP**

### **Affected Drugs**

TRUQAP™

### **Covered Uses**

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

### **Off-label Uses**

N/A

### **Exclusion Criteria**

Concomitant use of strong (e.g. rifampicin, etc.) and moderate (e.g., efavirenz, etc.) CYP3A inducers.

### **Required Medical Information**

Documented diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test (e.g., FoundationOne CDx, etc.), after progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy. Truqap will be used in combination with fulvestrant. Baseline CBC.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist, Hematologist

### **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.

## **VANFLYTA**

### **Affected Drugs**

VANFLYTA®

### **Covered Uses**

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

### **Off-label Uses**

N/A

### **Exclusion Criteria**

Severe hypokalemia. Severe hypomagnesemia. Long QT syndrome. History of ventricular arrhythmias or torsades de pointes.

### **Required Medical Information**

Documented diagnosis of newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay, etc.), to be used 1) in combination with standard cytarabine and anthracycline induction or cytarabine consolidation or 2) as maintenance monotherapy following consolidation chemotherapy. Baseline ECG, potassium, magnesium.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Oncologist, Hematologist

### **Coverage Duration**

The PA will be approved for lifetime.

### **Other Criteria**

N/A

## **VELPHORO**

### **Affected Drugs**

VELPHORO®

### **Covered Uses**

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

### **Off-label Uses**

N/A

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Velphoro will be used to control serum phosphorus levels in patients with chronic kidney disease on dialysis.

### **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

## **VERQUVO**

### **Affected Drugs**

VERQUVO®

### **Covered Uses**

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

### **Off-label Uses**

N/A

### **Exclusion Criteria**

Concomitant use with other soluble guanylate cyclase (sGC) stimulators.  
Concomitant use with PDE-5 Inhibitors. Pregnancy in females of reproductive potential.

### **Required Medical Information**

Documented diagnosis of symptomatic chronic heart failure in patients with ejection fraction less than 45%.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Cardiologist

### **Coverage Duration**

The PA will be approved for lifetime.

### **Other Criteria**

The use of at least of two other medications for heart failure (e.g., ACEI, ARB, beta-blocker, Entresto, aldosterone antagonist, diuretic, Corlanor, Farxiga, Jardiance, etc.) is required prior to the initiation of Verquvo.

## **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 10<sup>9</sup>/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 1) 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 or 2) advanced renal cell carcinoma following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI).

### **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. In patients with IgE-mediated food allergy, the use of prerequisite drugs is not required.

## **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

## **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.

## **ZURZUVAE**

### **Affected Drugs**

ZURZUVAE™

### **Covered Uses**

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

### **Off-label Uses**

N/A

### **Exclusion Criteria**

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

### **Required Medical Information**

Documented diagnosis of postpartum depression.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Obstetrician-Gynecologist, Psychiatrist

### **Coverage Duration**

The PA will be approved for 14 days

### **Other Criteria**

Onset of symptoms in the third trimester or within 4 weeks of delivery. Patient is less than or equal to 12 months postpartum.

## **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