# ABIRATERONE

## Products Affected

- *abiraterone acetate*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Castration-resistant metastatic prostate cancer and used in combination with prednisone, or B.) High risk, castration-sensitive metastatic prostate cancer and used in combination with prednisone |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or urologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ACITRETIN

## Products Affected

- *acitretin*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Severely impaired liver or kidney function, B.) Chronic abnormally elevated blood lipid values, C.) Concomitant use of methotrexate or tetracyclines, D.) Pregnancy |
| **Required Medical Information** | Diagnosis of severe, recalcitrant psoriasis (including plaque, guttate, erythrodermic palmar- plantar and pustular) AND patient must have tried and failed, contraindication or intolerance to one formulary first line agent (e.g., Topical Corticosteroids (betamethasone, fluocinonide, desoximetasone), Topical Calcipotriene, OR Topical Tazarotene) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ACTIMMUNE

## Products Affected

- ACTIMMUNE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Chronic granulomatous disease for use in reducing the frequency and severity of serious infections, or B.) Severe, malignant osteopetrosis (SMO) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ADEMPAS

## Products Affected

- ADEMPAS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Concomitant administration with nitrates or nitric oxide donors (such as amyl nitrate) in any form, B.) Concomitant administration with phosphodiesterase inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline), C.) Pregnancy, or D.) Patients with pulmonary hypertension associated with idiopathic interstitial pneumonia |
| **Required Medical Information** | Diagnosis of one of the following A.) Pulmonary arterial hypertension (WHO group I) and diagnosis was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.), or B.) Chronic thromboembolic pulmonary hypertension (CTEPH, WHO group 4) and patient has persistent or recurrent disease after surgical treatment (e.g., pulmonary endarterectomy) or has CTEPH that is inoperable (Female patients must be enrolled in the ADEMPAS REMS program) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cardiologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# AFINITOR DISPERZ

## Products Affected

- AFINITOR DISPERZ ORAL TABLET SOLUBLE 2 MG, 3 MG, 5 MG
- AFINITOR ORAL TABLET 10 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Requests for Afinitor disperz require a diagnosis of one of the following A.) Tuberous sclerosis complex (TSC)-associated partial-onset seizures, or B.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection. Request for Afinitor tabs require a diagnosis of one of the following A.) Renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, B.) Advanced hormone receptor-positive, HER2 negative breast cancer in postmenopausal women and taken in combination with exemestane, after failure with letrozole or anastrozole, C.) Progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin and disease is unresectable, locally advanced, or metastatic, D.) Pancreatic progressive neuroendocrine tumors and disease is unresectable, locally advanced, or metastatic, E.) Advanced renal cell carcinoma (RCC) after failure with sunitinib or sorafenib, F.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ALECENSA

## Products Affected

- ALECENSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer as detected by an FDA-approved test |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ALKINDI

## Products Affected

- ALKINDI SPRINKLE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Must meet all of the following 1.) Prescriber attests to a documented, adrenocortical insufficiency requiring hydrocortisone treatment and 2.) Prescriber attests patient has a need for dosage strengths and titration flexibility that are not available with other available formulations of hydrocortisone |
| **Age Restrictions** | 18 years of age and younger |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist or pediatrician |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ALOSETRON

## Products Affected

- *alosetron hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Constipation, B.) History of Chronic or severe constipation or sequelae from constipation, C.) History of ischemic colitis, intestinal obstruction, stricture, toxic megacolon, GI perforation, adhesions, diverticulitis, Crohns disease, ulcerative colitis, D.) History of severe hepatic impairment, E.) History of impaired intestinal circulation, thrombophlebitis, or hypercoagulable state, or F.) Coadministration with fluvoxamine |
| **Required Medical Information** | Diagnosis of irritable bowel syndrome, severe diarrhea-predominant |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ALPHA-1 PROTEINASE INHIBITOR

## Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency in adult patients with emphysema |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | B vs D determination required per CMS guidance |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ALUNBRIG

## Products Affected

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of anaplastic lymphoma kinase-positive (ALK) metastatic non-small cell lung cancer (NSCLC) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# AMBRISENTAN

## Products Affected

- *ambrisentan*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Pregnancy, or B.) Idiopathic pulmonary fibrosis (IPF), including those with pulmonary hypertension |
| **Required Medical Information** | Diagnosis of pulmonary arterial hypertension classified as WHO Group I, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cardiologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# APOKYN

## Products Affected

- APOKYN SUBCUTANEOUS SOLUTION CARTRIDGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with 5-HT(3) receptor antagonists (e.g. ondansetron, granisetron, dolasetron, palonosetron, alosetron etc.) |
| **Required Medical Information** | Diagnosis of Parkinson's disease (PD) and patient is experiencing acute intermittent hypomobility (defined as off episodes characterized by muscle stiffness, slow movements, or difficulty starting movements) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ARCALYST

## Products Affected

- ARCALYST

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells Syndrome (MWS), B.) Deficiency of interleukin-1 receptor antagonist (DIRA) and patient requires maintenance therapy for remission, or C.) Recurrent pericarditis (RP) and reduction in risk of recurrence |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# AURYXIA

## Products Affected

- AURYXIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Iron overload syndrome (e.g. hemochromatosis) |
| **Required Medical Information** | Diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or nephrologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Ferric Citrate is NOT approvable for iron deficiency anemia per Part D law |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# AUSTEDO

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Suicidal ideation and/or untreated or inadequately treated depression in patients with Huntington's disease, B.) Hepatic impairment, C.) Taking MAOIs, reserpine, or tetrabenazine |
| **Required Medical Information** | Diagnosis of one of the following A.) Chorea associated with Huntington's disease (Huntington's chorea), or B.) Tardive dyskinesia |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or psychiatrist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# AYVAKIT

## Products Affected

- AYVAKIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Unresectable or metastatic gastrointestinal stromal tumor, with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations, or B.) Advanced systemic mastocytosis (AdvSM), including patients with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, or mast cell leukemia |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# BALVERSA

## Products Affected

- BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 or FGFR2 genetic alterations and patient has progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or urologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# BENLYSTA

## Products Affected

- BENLYSTA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Active, autoantibody-positive, system lupus erythematosus (SLE), or B.) Active lupus nephritis and patient is receiving standard therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist or rheumatologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# BOSENTAN

## Products Affected

- *bosentan*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Concomitant cyclosporine A or glyburide therapy, or B.) Pregnancy |
| **Required Medical Information** | Diagnosis of pulmonary arterial hypertension (WHO Group I) and patient has New York Heart Association (NYHA) Functional Class II-IV, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with pulmonologist or cardiologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# BOSULIF

## Products Affected

- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or inadequate response to prior therapy, or B.) Newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) CML |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# BRAFTOVI

## Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) unresectable or metastatic melanoma with documented BRAF V600E or V600K mutation as detected by a FDA-approved test and used in combination with binimetinib, or B.) metastatic colorectal cancer with documented BRAF V600E mutation as detected by an FDA-approved test and patient has received prior therapy. Must be used in combination with cetuximab. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# BRUKINSA

## Products Affected

- BRUKINSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following: A.) mantle cell lymphoma (MCL) and patient has received at least one prior therapy or B.) treatment of adult patients with Waldenstrom macroglobulinemia or C.) treatment of adult patients with relapsed or refractory marginal zone lymphoma who have received at least one anti-CD20-based regimen |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CABOMETYX

## Products Affected

- CABOMETYX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Advanced hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib, C.) Advanced renal cell carcinoma and used as first line treatment in combination with nivolumab or D.) treatment of adults and pediatric patients 12 years and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible |
| **Age Restrictions** | DTC: 12 years of age and older. HCC: 18 years of age and older. RCC: 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CALCIPOTRIENE

## Products Affected

- *calcipotriene external cream*
- *calcipotriene external ointment*
- *calcipotriene external solution*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of psoriasis AND patient experienced an inadequate treatment response, intolerance, or contraindication to a generic topical steroid (i.e., betamethasone, fluocinonide, desoximetasone) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CALQUENCE

## Products Affected

- CALQUENCE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least 1 prior therapy, B.) Chronic lymphocytic leukemia (CLL), or C.) Small lymphocytic lymphoma (SLL) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CAPRELSA

## Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Congenital long QT syndrome |
| **Required Medical Information** | Diagnosis of metastatic or unresectable locally advanced medullary thyroid cancer (MTC) AND disease is symptomatic or progressive |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CARBAGLU

## Products Affected

- CARBAGLU

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) N-acetyl glutamate synthase (NAGS) deficiency with acute or chronic hyperammonemia, or B.) Propionic or methylmalonic acidemia with acute hyperammonemia |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CAYSTON

## Products Affected

- CAYSTON

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has suspected or confirmed Pseudomonas aeruginosa infection |
| **Age Restrictions** | 7 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CERDELGA

## Products Affected

- CERDELGA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of Gaucher disease type 1 and patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CINRYZE

## Products Affected

- CINRYZE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of hereditary angioedema (HAE) and used as routine prophylaxis against angioedema attacks |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist, immunologist, or allergist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CNS STIMULANTS

## Products Affected

- *modafinil oral tablet 100 mg, 200 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Obstructive sleep apnea (OSA) confirmed by sleep lab evaluation, B.) Narcolepsy confirmed by sleep lab evaluation, or C.) Shift work disorder (SWD) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# COMETRIQ

## Products Affected

- COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of progressive, metastatic medullary thyroid cancer |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# COPIKTRA

## Products Affected

- COPIKTRA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A) chronic lymphocytic leukemia, OR B) small lymphocytic lymphoma, OR C) follicular lymphoma, AND disease is relapsed or refractory, AND patient has history of at least 2 prior therapies |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# COSENTYX

## Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 75 MG/0.5ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Ankylosing spondylitis and patient has failed or is intolerant to Humira and Enbrel, B.) Moderate to severe plaque psoriasis in adults and patient has failed or is intolerant to Humira and Enbrel, C.) Moderate to severe plaque psoriasis in patients 6 years to less than 18 years of age and patient has failed or is intolerant to Enbrel, D.) Active psoriatic arthritis and patient has failed or is intolerant to Humira and Enbrel, or E.) Non-radiographic axial spondyloarthritis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# COTELLIC

## Products Affected

- COTELLIC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of unresectable or metastatic malignant melanoma with BRAF V600E OR V600K mutation, and documentation of combination therapy with vemurafenib (Zelboraf) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CYPROHEPTADINE

## Products Affected

- *cyproheptadine hcl oral*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following: A.) Breastfeeding, B.) Concurrent use with MAOIs or within 14 days of MAOI therapy, C.) Angle-closure glaucoma, D.) Stenosing peptic ulcer, E.) Symptomatic prostatic hypertrophy, F.) Bladder neck obstruction, G.) Pyloroduodenal obstruction |
| **Required Medical Information** | Diagnosis of one of the following: A.) Perennial or seasonal allergic rhinitis, B.) Vasomotor rhinitis, C.) Allergic conjunctivitis, D.) Allergic skin manifestations of urticaria or angioedema, E.) Allergic reactions to blood or plasma, F.) Cold urticaria, G.) Dermatographism, or H.) Use as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled. |
| **Age Restrictions** | 2 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CYSTADROPS

## Products Affected

- CYSTADROPS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Demonstrated cysteamine hypersensitivity, B.) Demonstrated penicillamine hypersensitivity |
| **Required Medical Information** | Diagnosis of cystinosis and patient has corneal cystine crystal accumulation |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CYSTAGON

## Products Affected

- CYSTAGON

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Known serious hypersensitivity to penicillamine or cysteamine |
| **Required Medical Information** | Diagnosis of nephropathic cystinosis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# CYSTARAN

## Products Affected

- CYSTARAN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Demonstrated cysteamine hypersensitivity, B.) Demonstrated penicillamine hypersensitivity |
| **Required Medical Information** | Diagnosis of cystinosis and patient has corneal cystine crystal accumulation |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DALFAMPRIDINE

## Products Affected

- *dalfampridine er*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) History of seizure. B.) Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute) |
| **Required Medical Information** | Diagnosis of multiple sclerosis and patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting dalfampridine |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DAURISMO

## Products Affected

- DAURISMO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of newly diagnosed acute myeloid leukemia (AML) and used in combination with cytarabine in patients 75 years of age or older OR in patients that have comorbidities that preclude use of intensive induction chemotherapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DEFERASIROX

## Products Affected

- *deferasirox granules*
- *deferasirox oral tablet*
- *deferasirox oral tablet soluble*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Creatinine clearance less than 40 mL/min, B.) Poor performance status, C.) Platelet count less than 50 x 10(9)/L, D.) Advanced malignancy, E.) High-risk myelodysplastic syndrome (MDS) |
| **Required Medical Information** | Diagnosis of one of the following A.) Chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes who have liver iron concentrations of at least 5 mg Fe/g dry weight AND serum ferritin level greater than 300 mcg/L, or B.) Chronic iron overload due to blood transfusions (transfusion hemosiderosis) as evidenced by transfusion of at least 100 mL/kg packed red blood cells AND serum ferritin level greater than 1000 mcg/L |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DEFERIPRONE

## Products Affected

- *deferiprone*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Must meet all of the following 1.) Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias, 2.) Patient has failed prior chelation therapy, and 3.) Patient has an absolute neutrophil count greater than 1.5 x 10(9)/L |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DIACOMIT

## Products Affected

- DIACOMIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of severe myoclonic epilepsy in infancy (Dravet syndrome) in patients taking clobazam |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DICLOFENAC PATCH

## Products Affected

- *diclofenac epolamine external*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of acute mild to moderate pain due to minor strains, sprains and contusions |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DIMETHYL FUMARATE

## Products Affected

- *dimethyl fumarate oral*
- *dimethyl fumarate starter pack*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DOJOLVI

## Products Affected

- DOJOLVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of Long-chain fatty acid oxidation disorder (LC-FAOD) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DRONABINOL

## Products Affected

- *dronabinol*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Sesame oil hypersensitivity |
| **Required Medical Information** | Diagnosis of one of the following A.) Anorexia associated to AIDS, or B.) Chemotherapy-induced nausea and vomiting |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | B vs D determination required per CMS guidance |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DROXIDOPA

## Products Affected

- *droxidopa*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (e.g., Parkinson disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# DUPIXENT

## Products Affected

- DUPIXENT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent therapy with another biologic medication [e.g., Xolair (omalizumab), Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)] |
| **Required Medical Information** | Diagnosis of one of the following A.) Moderate to Severe Atopic Dermatitis, B.) Moderate to Severe Asthma, or C.) Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) |
| **Age Restrictions** | Asthma: 6 years of age or older. Atopic Dermatitis: 6 years of age or older. Chronic Rhinosinusitis with Nasal Polyposis: 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, asthma specialist, dermatologist, ENT specialist, immunologist, otolaryngologist, or pulmonologist. |
| **Coverage Duration** | INITIAL: Atopic Dermatitis,CRSwNP: 6 months. Asthma:12 months RENEWAL: 12 months (All indications) |
| **Other Criteria** | A.) Moderate to Severe Atopic Dermatitis INITIAL: 1.) Patient has documented diagnosis of moderate to severe atopic dermatitis AND 2.) Prescriber attests that patient has greater than or equal to 10% body surface area (BSA) involvement AND 3.) Must have tried and failed or has a contraindication or intolerance to a 6 week trial of at least two of the following formulary options: a.) Very high or high potency topical steroid, b.) Tacrolimus ointment or pimecrolimus cream, OR c.) An immunosuppressive agent. RENEWAL: Documentation that the patient has responded to Dupixent as determined by the prescriber (e.g., marked improvements in erythema, induration, papulation, edema, excoriations, and lichenification, reduced pruritus, decreased requirement for other topical or systemic therapies, reduced body surface area affected with atopic dermatitis, or other responses observed). B.) Moderate to Severe Asthma INITIAL: 1.) Patient has moderate to severe asthma defined as current drug therapy including a.) A medium, high-dose, or max-tolerated inhaled corticosteroid (ICS) AND one additional asthma controller medication (long-acting beta 2-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist (LTRA), or theophylline) OR b.) Maximally tolerated ICS/LABA combination product |

| PA Criteria | Criteria Details |
|---|---|
| | AND 2.) Patient's peripheral blood eosinophil (EOS) count is greater than or equal to 150 cells per microliter AND 3.) Patient has had one asthma exacerbation in previous 12 months (e.g. oral corticosteroid (OCS) burst, ER visit, hospital admission, urgent care visit) OR is dependent on chronic daily OCS for asthma control. RENEWAL: Treatment has resulted in clinical benefit defined as one or more of the following: a.) Decreased use of oral corticosteroids, b.) Increase in Forced Expiratory Volume (FEV1) from pretreatment baseline, c.) Decreased use of inhaled corticosteroid use, d.) Decrease in hospitalizations, e.) Decrease in ER visits, OR f.) Decrease in unscheduled visits to healthcare provider. C.) Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) INITIAL: 1.) Patient has a documented diagnosis of CRSwNP with the presence of nasal polyps AND 2.) Patient has two or more of the following symptoms for greater than or equal to 12 weeks: a.) mucopurulent discharge, b.) nasal obstruction and congestion, c.) decreased or absent sense of smell, OR d.) facial pressure or pain AND 3.) Patient is unable to achieve symptom relief after trial of intranasal corticosteroids AND 4.) Patient will continue to use Dupixent in combination with intranasal corticosteroid therapy. RENEWAL: Patient has responded to Dupixent as determined by the prescribing physician. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# EMGALITY

## Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Chronic or episodic migraine disorder and patient has documented trial, inadequate response, or contraindication to at least 1 generic beta-blocker agent or generic anti-epileptic agent used in migraine prevention (i.e., propranolol, topiramate, valproic acid, divalproex), or B.) Episodic cluster headache |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ENBREL

## Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following: A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, or E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ENDARI

## Products Affected

- ENDARI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Acute sickle cell disease, or B.) Short bowel syndrome and combined with recombinant human growth hormone |
| **Age Restrictions** | 5 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ENSPRYNG

## Products Affected

- ENSPRYNG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Active Hepatitis B infection, or B.) Active or untreated latent tuberculosis |
| **Required Medical Information** | Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist, immunologist, or ophthalmologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# EPIDIOLEX

## Products Affected

- EPIDIOLEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Lennox-Gastaut syndrome, or B.) Severe myoclonic epilepsy in infancy (Dravet syndrome), or C.) Seizures associated with tuberous sclerosis complex |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# EPOETIN THERAPY

## Products Affected

- RETACRIT INJECTION SOLUTION 10000 UNIT/ML, 10000 UNIT/ML(1ML), 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 40000 UNIT/ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Supporting statement of diagnosis from physician |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | B vs D determination required per CMS guidance |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ERIVEDGE

## Products Affected

- ERIVEDGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Metastatic basal cell carcinoma, or B.) Locally advanced basal cell carcinoma that has recurred following surgery or the patient is not a candidate for surgery or radiation |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ERLEADA

## Products Affected

- ERLEADA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Nonmetastatic, castration-resistant prostate cancer, or B.) Metastatic, castration-sensitive prostate cancer |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or urologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ERLOTINIB

## Products Affected

- *erlotinib hcl oral tablet 100 mg, 150 mg, 25 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Locally advanced, unresectable, or metastatic pancreatic cancer and erlotinib will be used in combination with gemcitabine, or B.) Locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility AND one of the following 1.) erlotinib will be used as first-line treatment, OR 2.) failure with at least one prior chemotherapy regimen, OR 3.) no evidence of disease progression after four cycles of first-line platinum-based chemotherapy and erlotinib will be used as maintenance treatment |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ESBRIET

## Products Affected

- ESBRIET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of idiopathic pulmonary fibrosis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# EVEROLIMUS

## Products Affected

- *everolimus oral tablet 2.5 mg, 5 mg, 7.5 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, B.) Advanced hormone receptor-positive, HER2 negative breast cancer in postmenopausal women and taken in combination with exemestane, after failure with letrozole or anastrozole, C.) Progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin and disease is unresectable, locally advanced, or metastatic, D.) Pancreatic progressive neuroendocrine tumors and disease is unresectable, locally advanced, or metastatic, E.) Advanced renal cell carcinoma (RCC) after failure with sunitinib or sorafenib, F.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# EVRYSDI

## Products Affected

- EVRYSDI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of spinal muscular atrophy (SMA) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# FARYDAK

## Products Affected

- FARYDAK ORAL CAPSULE 10 MG, 15 MG, 20 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Must meet all of the following 1.) Diagnosis of multiple myeloma, 2.) Medication is being used in combination with Velcade (bortezomib) and dexamethasone, 3.) Patient has received at least two prior treatment regimens, including Velcade (bortezomib) and an immunomodulatory agent [e.g., Revlimid (lenalidomide), Thalomid (thalidomide)] |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# FEBUXOSTAT

## Products Affected

- *febuxostat*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use of azathioprine or mercaptopurine |
| **Required Medical Information** | Diagnosis of Gout and all of the following 1.) documented inadequate treatment response, adverse event, or contraindication to maximally titrated dose of Allopurinol, and 2.) patients with established cardiovascular disease, prescriber attests that benefit of treatment outweighs the risk of treatment |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# FENTANYL ORAL

## Products Affected

- *fentanyl citrate buccal lozenge on a handle*
- *fentanyl citrate buccal tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Use in opioid non-tolerant patients |
| **Required Medical Information** | Must meet all of the following 1.) Diagnosis of cancer-related breakthrough pain, 2.) Patient is currently receiving/tolerant to around-the-clock opioid therapy for persistent cancer pain, and 3.) Patient and prescriber are enrolled in the TIRF REMS Access Program |
| **Age Restrictions** | 16 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# FERRIPROX

## Products Affected

- FERRIPROX ORAL SOLUTION
- FERRIPROX ORAL TABLET 1000 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Must meet all of the following 1.) Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias, 2.) Patient has failed prior chelation therapy, and 3.) Patient has an absolute neutrophil count greater than 1.5 x 10(9)/L |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# FINTEPLA

## Products Affected

- FINTEPLA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI |
| **Required Medical Information** | Diagnosis of Severe myoclonic epilepsy in infancy (Dravet syndrome) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# FORTEO

## Products Affected

- FORTEO SUBCUTANEOUS SOLUTION PEN-INJECTOR 620 MCG/2.48ML
- *teriparatide (recombinant)*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Patient has previous trial and failure, contraindication, or intolerance to a bisphosphonate AND diagnosis of one of the following A.) osteoporosis in postmenopausal female patient with high risk for fracture and patient has history of or contraindication to Tymlos, B.) primary or hypogonadal osteoporosis in male patient with high risk for fracture, or C.) osteoporosis due to associated sustained systemic glucocorticoid therapy in patient with high risk for fracture |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months (Maximum 24 month treatment per patient lifetime) |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# FOTIVDA

## Products Affected

- FOTIVDA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of relapsed or refractory advanced renal cell cancer (RCC) following 2 or more prior systemic therapies |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# GATTEX

## Products Affected

- GATTEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of short bowel syndrome and patient is dependent on parenteral support |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# GAVRETO

## Products Affected

- GAVRETO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test, B.) Advanced or metastatic RET-mutant medullary thyroid cancer and patient requires systemic therapy, or C.) Advanced or metastatic RET fusion-positive thyroid and patient requires systemic therapy and is radioactive iodine-refractory, when radioactive iodine is appropriate |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# GILENYA

## Products Affected

- GILENYA ORAL CAPSULE 0.5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure, B.) History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker, C.) Baseline QTC interval greater than or equal to 500 milliseconds, D.) Receiving concurrent treatment with Class Ia or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol) |
| **Required Medical Information** | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| **Age Restrictions** | 10 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# GILOTRIF

## Products Affected

- GILOTRIF

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have nonresistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test, or B.) Metastatic squamous NSCLC with progression after platinum-based chemotherapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# GLATIRAMER

## Products Affected

- *glatiramer acetate subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# GOCOVRI

## Products Affected

- GOCOVRI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Patients with end-stage renal disease (ESRD, CrCl below 15 ml/min/m2) |
| **Required Medical Information** | Diagnosis of one of the following A.) Parkinson disease and patient is experiencing dyskinesia, receiving levodopa based therapy, and has documented trial and failure to amantadine immediate release, B.) Extrapyramidal disease and has documented trial and failure to amantadine immediate release, or C.) Parkinson disease and patient is experiencing "off" episodes, receiving levodopa/carbidopa based therapy, and has documented trial and failure to amantadine immediate release |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# GROWTH HORMONE

## Products Affected

- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Use for growth promotion in pediatric patients with closed epiphyses, B.) Acute critical illness caused by complications following open-heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure, C.) Active malignancy, D.) Active proliferative or severe nonproliferative diabetic retinopathy, E.) Prader-Willi Syndrome in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment |
| **Required Medical Information** | Diagnosis of pediatric indication: A.) GHD and bone age at least 1 year or 2 standard deviations (SD) delayed compared with chronological age and 2 stim tests with peak GH secretion below 10 ng/mL or IGF-1/IGFBP3 level more than 2 SDS below mean if CNS pathology, h/o irradiation, or proven genetic cause, B.) SGA and birth weight or length 2 or more SDS below mean for gestational age and fails to manifest catch up growth by age 2 (height 2 or more SDS below mean for age and gender), C.) CRI and nutritional status has been optimized, metabolic abnormalities have been corrected, and patient has not had renal transplant D.) SHOX deficiency or Noonan syndrome E.) PWS confirmed by genetic testing, F.) Turner Syndrome confirmed by chromosome analysis. For GHD, CRI, SHOX deficiency, Noonan syndrome, and PWS one of the following height more than 3 SDS below mean for age and gender, or height more than 2 SDS below mean with GV more than 1 SDS below mean, or GV over 1 year 2 SDS below mean. OR Diagnosis of an adult indication: A.) childhood- or adult-onset GHD confirmed by 2 standard GH stim tests (provide assay): 1 test must be insulin tolerance test (ITT) with blood glucose nadir less than 40 mg/dL (2.2 mmol/L). If contraindicated, use a standardized stim test (i.e. arginine plus GH releasing hormone [preferred], glucagon, arginine), B.) GHD with at least 1 other pituitary hormone deficiency and failed at least 1 GH stim test (ITT preferred), C.) GHD with panhypopituitarism (3 or more pituitary hormone deficiencies), D.) GHD with irreversible hypothalamic-pituitary structural lesions due to tumors, surgery or radiation of pituitary or hypothalamus region AND a subnormal IGF-1 (after at least 1 month off GH therapy) AND Objective evidence of GHD complications, such as: low bone density, increased visceral fat mass, or cardiovascular complications AND Completed linear growth (GV less than |

| PA Criteria | Criteria Details |
|---|---|
| | 2 cm/year) AND GH has been discontinued for at least 1 month (if previously receiving GH) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an Endocrinologist or Nephrologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# HAEGARDA

## Products Affected

- HAEGARDA SUBCUTANEOUS SOLUTION RECONSTITUTED 2000 UNIT, 3000 UNIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of hereditary angioedema (HAE) and used as routine prophylaxis against angioedema attacks |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist, immunologist, or allergist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# HEMADY

## Products Affected

- HEMADY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Systemic fungal infections |
| **Required Medical Information** | Diagnosis of multiple myeloma (MM), used in combination with other anti-myeloma drugs, and treatment regimen cannot be supported by lower strengths of oral dexamethasone |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# HEPATITIS B

## Products Affected

- *adefovir dipivoxil*
- BARACLUDE ORAL SOLUTION
- *entecavir*
- VEMLIDY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of chronic hepatitis B and all of the following 1.) Patient has evidence of viral replication, 2.) Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) or histologically active disease, and 3.) Patient is receiving anti-retroviral therapy if the patient has HIV co-infection |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# HEPATITIS C

## Products Affected

- MAVYRET
- VOSEVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of HCV genotype, subtype and quantitative HCV RNA (viral load) testing any time prior to therapy. Must document cirrhosis status, prior treatment history (if any), and planned duration of treatment. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist |
| **Coverage Duration** | Duration of approval per AASLD Guidelines |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# HETLIOZ

## Products Affected

- HETLIOZ
- HETLIOZ LQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Non-24-hour-sleep-wake disorder (Non-24), or B.) Nighttime sleep disturbances associated with Smith-Magenis Syndrome (SMS) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# HUMIRA

## Products Affected

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS PREFILLED SYRINGE KIT 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PEDIATRIC UC START
- HUMIRA PEN-PS/UV/ADOL HS START SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML
- HUMIRA PEN-PSOR/UVEIT STARTER
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following: A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Non-infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# IBRANCE

## Products Affected

- IBRANCE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with fulvestrant and disease has progressed following endocrine therapy, or B.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with an aromatase inhibitor in postmenopausal women or men |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ICATIBANT

## Products Affected

- *icatibant acetate*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of hereditary angioedema (HAE) and medication will be used for the treatment of acute attacks |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist, immunologist, or allergist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ICLUSIG

## Products Affected

- ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated, B.) Chronic phase, chronic myeloid leukemia (CML) in adult patients with resistance or intolerance to at least two prior kinase inhibitors, or C.) Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# IDHIFA

## Products Affected

- IDHIFA ORAL TABLET 100 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase 2 (IDH2) mutation as detected by an FDA approved test |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# IMATINIB

## Products Affected

- *imatinib mesylate oral tablet 100 mg, 400 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), B.) Ph+ acute lymphoblastic leukemia (ALL), C.) Gastrointestinal stromal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy, D.) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, E.) Hypereosinophilic syndrome or chronic eosinophilic leukemia, F.) Myelodysplastic syndrome or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements, or G.) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# IMBRUVICA

## Products Affected

- IMBRUVICA ORAL CAPSULE
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG, 560 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least one prior therapy, B.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL), C.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion, D.) Waldenstrom's macroglobulinemia (WM), E.) Marginal zone lymphoma (MZL) and patient requires systemic therapy and has received at least one prior anti-CD20-based therapy, or F.) Chronic graft vs host disease (cGVHD) after failure of a least one first-line corticosteroid therapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# INCRELEX

## Products Affected

- INCRELEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following: A.) active or suspected malignancy, B.) use for growth promotion in patients with closed epiphyses, C.) Intravenous administration |
| **Required Medical Information** | Prescribed for treatment of growth failure in pediatric patient AND patient has diagnosis of one of the following A.) Severe primary insulin-like growth factor-1 (IGF-1) deficiency, or B.) Growth hormone (GH) gene deletion and patient has developed neutralizing antibodies to GH |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# INGREZZA

## Products Affected

- INGREZZA ORAL CAPSULE
- INGREZZA ORAL CAPSULE THERAPY PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Patient has a diagnosis of moderate to severe tardive dyskinesia |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or psychiatrist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# INLYTA

## Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Advanced renal cell carcinoma and patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens), or B.) Advanced renal cell carcinoma and used as first-line therapy in combination with avelumab or pembrolizumab |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# INQOVI

## Products Affected

- INQOVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | 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 |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# INREBIC

## Products Affected

- INREBIC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF). |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# INTRAROSA

## Products Affected

- INTRAROSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Vaginal bleeding or dysfunctional uterine bleeding of an undetermined origin, or B.) Known or suspected estrogen-dependent neoplasia |
| **Required Medical Information** | Diagnosis of one of the following A.) moderate to severe dyspareunia due to menopause, or B.) atrophic vaginitis due to menopause |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 3 months, Renewal: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# INTRON A

## Products Affected

- INTRON A

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Autoimmune hepatitis, B.) Decompensated liver disease |
| **Required Medical Information** | Diagnosis of one of the following A.) Hairy cell leukemia, B.) Condylomata acuminata involving external surfaces to the genital or perianal areas, C.) AIDS-related Kaposi's sarcoma, D.) Clinically aggressive follicular lymphoma and the medication will be used concurrently with anthracycline-containing chemotherapy or is not a candidate for anthracycline-containing chemotherapy, E.) Malignant melanoma and the request for coverage is within 56 days of surgery and the patient is at high risk of disease recurrence, F.) Chronic hepatitis B with compensated liver disease and patient has evidence of hepatitis B viral replication and patient has been serum hepatitis B surface antigen-positive for at least 6 months, or G.) Chronic hepatitis C with compensated liver disease and is receiving combination therapy with ribavirin, unless ribavirin is contraindicated, and the medication will not be used as part of triple therapy with a protease inhibitor and patient has a clinical reason for not using peginterferon |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Condylomata: 3 months, HBV E antigen positive and Kaposi sarcoma: 16 weeks, Other: 12 months |
| **Other Criteria** | B vs D determination required per CMS guidance |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# IRESSA

## Products Affected

- IRESSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of metastatic non-small cell lung cancer (NSCLC) and must meet both of the following 1.) tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility, AND 2.) Used as first-line treatment |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ISTURISA

## Products Affected

- ISTURISA ORAL TABLET 1 MG, 10 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of Cushing's disease in patients for whom pituitary surgery is not an option or has not been curative |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ITRACONAZOLE

## Products Affected

- *itraconazole oral*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF), B.) Concurrent therapy with a CYP3A4 substrate (e.g., methadone, lovastatin, simvastatin, etc.) |
| **Required Medical Information** | Diagnosis of one of the following A.) Systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), or B.) Onychomycosis confirmed by one of the following positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# JAKAFI

## Products Affected

- JAKAFI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis, B.) Polycythemia vera AND patient has had an inadequate response to or is intolerant of hydroxyurea, C.) Acute graft versus host disease AND disease is refractory to steroid therapy, OR D.) Chronic graft versus host disease after failure of 1 or 2 lines of systemic therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# JUXTAPID

## Products Affected

- JUXTAPID

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests, B.) Pregnancy, or C.) Concomitant use with strong or moderate CYP3A4 inhibitors |
| **Required Medical Information** | Diagnosis of HoFH as confirmed by one of the following A.) Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (LDLRAP1 or ARH), or B.) Both of the following 1.) Either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL, and 2.) Either xanthoma before 10 years of age or evidence of heterozygous FH in both parents |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# KALYDECO

## Products Affected

- KALYDECO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of cystic fibrosis (CF) and the patient has 1 mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# KESIMPTA

## Products Affected

- KESIMPTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Active Hepatitis B infection |
| **Required Medical Information** | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# KISQALI

## Products Affected

- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)
- KISQALI FEMARA (400 MG DOSE)
- KISQALI FEMARA (600 MG DOSE)
- KISQALI FEMARA(200 MG DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in pre/perimenopausal or postmenopausal women and used in combination with an aromatase inhibitor, or B.) Hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in postmenopausal women and used in combination with fulvestrant |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# KORLYM

## Products Affected

- KORLYM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) pregnancy, B.) coadministration with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, C.) concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses, D.) history of unexplained vaginal bleeding, E.) endometrial hyperplasia with atypia or endometrial carcinoma |
| **Required Medical Information** | Diagnosis of endogenous Cushing syndrome in patients with type 2 diabetes mellitus or glucose intolerance and both of the following 1.) Used to control hyperglycemia secondary to hypercortisolism, AND 2.) Patient has failed or is not a candidate for surgery |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# KOSELUGO

## Products Affected

- KOSELUGO ORAL CAPSULE 10 MG, 25 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of neurofibromatosis type 1 (NF1) in a patient who has symptomatic, inoperable plexiform neurofibromas (PN) |
| **Age Restrictions** | 2 years of age to 17 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LAPATINIB

## Products Affected

- *lapatinib ditosylate*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of advanced or metastatic breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND meets one of the following A.) Used in combination with capecitabine in a patient who has received prior therapy including an anthracycline, a taxane, and trastuzumab, OR B.) Used in combination with letrozole in a postmenopausal female for whom hormonal therapy is indicated |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LENVIMA

## Products Affected

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, B.) Advanced renal cell carcinoma, in combination with everolimus, following one prior anti-angiogenic therapy, C.) Advanced renal cell carcinoma, in combination with pembrolizumab D.) Unresectable hepatocellular carcinoma, first-line therapy, or E.) Advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, in combination with pembrolizumab, when disease has progressed following prior systemic therapy AND patient is not a candidate for curative surgery or radiation |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LEUKINE

## Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Patient has undergone allogeneic or autologous bone marrow transplant (BMT) and engraftment is delayed or failed, B.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, C.) Medication will be used for myeloid reconstitution after an autologous or allogeneic BMT, D.) Patient has acute myeloid leukemia and administration will be after completion of induction chemotherapy, E.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS) or F.) Autologous peripheral blood stem cell transplant, Following myeloablative chemotherapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LEUPROLIDE

## Products Affected

- ELIGARD
- *leuprolide acetate injection*
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), B.) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only), C.) Anemia due to uterine leiomyomata (Fibroids) (3.75 mg 1-month &11.25 mg 3-month depots only) and patient is preoperative, or D.) Central precocious puberty (idiopathic or neurogenic) in children |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | B vs D determination required per CMS guidance |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LIDOCAINE EXT

## Products Affected

- *lidocaine external ointment 5 %*
- *lidocaine hcl external solution*
- *lidocaine hcl urethral/mucosal external gel*
- *lidocaine-prilocaine external cream*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Amide hypersensitivity |
| **Required Medical Information** | For topical anesthesia of skin and mucous membranes |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 months |
| **Other Criteria** | B vs D determination required per CMS guidance |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LIDOCAINE PATCH

## Products Affected

- *lidocaine external patch 5 %*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Pain associated with diabetic neuropathy, B.) Pain associated with cancer-related neuropathy, C.) Post-herpetic neuralgia, D.) Back pain, or E.) Osteoarthritis of the knee or hip |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LINEZOLID

## Products Affected

- *linezolid intravenous solution 600 mg/300ml*
- *linezolid oral*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use of MAOI therapy |
| **Required Medical Information** | Diagnosis of one of the following A.) Community acquired pneumonia, B.) Hospital-acquired pneumonia, C.) Vancomycin-resistant Enterococcus faecium infection, D.) Complicated skin and skin structure infections, or E.) Uncomplicated skin and skin structure infections |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 1 month |
| **Other Criteria** | B vs D determination required per CMS guidance |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LONSURF

## Products Affected

- LONSURF

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Metastatic colorectal cancer, previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based regimens, an anti-VEGF therapy, and if RAS wild-type, an anti-EGFR therapy, or B.) Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LORBRENA

## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with strong CYP3A4 inducers |
| **Required Medical Information** | For metastatic non-small cell lung cancer (NSCLC), patient's tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LUMAKRAS

## Products Affected

- LUMAKRAS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) as determined by an FDA-approved test and patient has received at least one prior systemic therapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LUPKYNIS

## Products Affected

- LUPKYNIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin), or B.) Combination therapy with cyclophosphamide. |
| **Required Medical Information** | Diagnosis of systemic lupus erythematosus (SLE) with active lupus nephritis (LN) Classes III, IV, V (alone or in combination), and all of the following: 1.) Baseline renal function of 45 mL/min/1.73 m2 or greater, 2.) Will be used in combination with a background immunosuppressive therapy regimen (e.g. mycophenolate, oral steroids, etc). |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a rheumatologist or nephrologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# LYNPARZA

## Products Affected

- LYNPARZA ORAL TABLET 100 MG, 150 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) HER2-negative, deleterious or suspected deleterious germline BRCA mutated metastatic breast cancer AND patient has been previously treated with chemotherapy in neoadjuvant, adjuvant, or metastatic setting, B.) Advanced ovarian cancer with known or suspected BRCA mutation as detected by an FDA-approved test AND patient has trial and failure, contraindication, or intolerance to 3 or more prior lines of chemotherapy, C.) Recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer AND used for maintenance treatment in patients who are in complete or partial response to platinum-based chemotherapy (e.g. cisplatin, carboplatin), D.) Deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients with complete or partial response to first-line platinum-based chemotherapy, E.) Deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma and disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen, F.) Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA-mutation, and/or genomic instability. Used in combination with bevacizumab for maintenance treatment., or G.) Deleterious or suspected deleterious germline or somatic homologous recombination repair gene mutated metastatic castration-resistant prostate cancer in patients who have progressed following prior treatment with enzalutamide or abiraterone. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# MATULANE

## Products Affected

- MATULANE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Inadequate marrow reserve |
| **Required Medical Information** | Diagnosis of Hodgkin's Disease, Stages III and IV and used in combination with other anticancer drugs |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# MAYZENT

## Products Affected

- MAYZENT
- MAYZENT STARTER PACK ORAL TABLET THERAPY PACK 12 X 0.25 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) CYP2C9*3/*3 genotype, B.) In the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III-IV heart failure, or C.) Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker |
| **Required Medical Information** | Diagnosis of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease and the following A.) Patients with relapsing forms of multiple sclerosis have history of/or contraindication to Avonex, Betaseron, Glatiramer, Gilenya, or Dimethyl Fumarate (Tecfidera) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# MEKINIST

## Products Affected

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and used in combination with dabrafenib and no locoregional treatment options, B.) Malignant melanoma with lymph node involvement and following complete resection with BRAF V600E or V600K mutations and used in combination with dabrafenib, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutations and used in combination with dabrafenib or as monotherapy , or D.) Metastatic non-small cell lung cancer, with BRAF V600E mutation, in combination with dabrafenib |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# MEKTOVI

## Products Affected

- MEKTOVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of unresectable or metastatic malignant melanoma with documented BRAF V600E or V600K mutation as detected by an FDA approved test AND used in combination with encorafenib |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# METYROSINE

## Products Affected

- *metyrosine*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) pheochromocytoma and used for short-term management in patients who are awaiting surgery, or B.) malignant pheochromocytoma and used for long-term management when surgery is contraindicated |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# MIGLUSTAT

## Products Affected

- *miglustat*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of mild to moderate type 1 Gaucher disease and patient is not a candidate for enzyme replacement therapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# MS INTERFERONS

## Products Affected

- AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT
- AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT
- BETASERON SUBCUTANEOUS KIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# MYTESI

## Products Affected

- MYTESI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of non-infectious diarrhea associated with HIV/AIDS in patients receiving anti-retroviral therapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist or gastroenterologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# NATPARA

## Products Affected

- NATPARA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of hypoparathyroidism and used to control hypocalcemia |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# NERLYNX

## Products Affected

- NERLYNX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Early stage HER2-positive breast cancer and used following adjuvant trastuzumab therapy, or B.) Advanced or metastatic HER2-positive breast cancer, used in combination with capecitabine, AND patient has received 2 or more prior anti-HER2-based regimens in the metastatic setting |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# NEXAVAR

## Products Affected

- NEXAVAR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Squamous cell lung cancer being treated with carboplatin and paclitaxel |
| **Required Medical Information** | Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment, or C.) Unresectable hepatocellular carcinoma |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# NINLARO

## Products Affected

- NINLARO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of multiple myeloma, used in combination with lenalidomide and dexamethasone, AND patient has history of at least 1 prior therapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# NITISINONE

## Products Affected

- *nitisinone*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of hereditary tyrosinemia type 1 |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# NOXAFIL

## Products Affected

- NOXAFIL ORAL SUSPENSION

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Concomitant treatment with sirolimus, B.) Concomitant use of CYP3A4 substrates that prolong QT interval (pimozide, quinidine), C.) Concomitant use of HMG-CoA Reductase inhibitors primarily metabolized through CYP3A4, or D.) Concomitant use of ergot alkaloids |
| **Required Medical Information** | Diagnosis of one of the following A.) Oropharyngeal candidiasis, B.) Patient is severely immunocompromised and requires prophylaxis of invasive aspergillosis or candidiasis due to high risk of infection, or C.) Invasive aspergillosis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# NUBEQA

## Products Affected

- NUBEQA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of non-metastatic, castration-resistant prostate cancer |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or urologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# NUCALA

## Products Affected

- NUCALA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Severe asthma with eosinophilic phenotype, B.) Eosinophilic granulomatosis with polyangiitis (EGPA), C.) Hypereosinophilic syndrome lasting at least 6 months without an identifiable non-hematologic secondary cause, or D.) chronic rhinosinusitis with nasal polyps in adult patients with inadequate response to nasal corticosteroids. |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, hematologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# NUEDEXTA

## Products Affected

- NUEDEXTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) History of prolonged QT interval, congenital long QT syndrome or Torsades de pointes, B.) Heart failure, C.) Complete AV block without an implanted pacemaker or high risk of complete AV block, D.) Concomitant use with quinidine, quinine, mefloquine, or drugs that prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), E.) Concomitant use with MAOIs or within 14 days of MAOI therapy |
| **Required Medical Information** | Diagnosis of pseudobulbar affect |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# NUPLAZID

## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of hallucinations and delusions associated with Parkinson disease psychosis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# OCTREOTIDE

## Products Affected

- *octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Acromegaly and patient has inadequate response to or is ineligible for surgery, radiation, or bromocriptine mesylate, or B.) Metastatic carcinoid syndrome, or C.) Vasoactive intestinal peptide-secreting tumors (VIPomas) with associated diarrhea |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ODOMZO

## Products Affected

- ODOMZO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Pregnancy |
| **Required Medical Information** | Diagnosis of locally advanced basal cell carcinoma of the skin and one of the following A.) Cancer has recurred following surgery or radiation therapy, B.) Patient is not a candidate for surgery or radiation therapy. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# OFEV

## Products Affected

- OFEV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Idiopathic pulmonary fibrosis (IPF), B.) Systemic sclerosis-associated interstitial lung disease (ILD), or C.) Chronic fibrosing interstitial lung disease with a progressive phenotype |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ONUREG

## Products Affected

- ONUREG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of acute myeloid leukemia (AML) used in maintenance treatment for adult patients who 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 |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# OPSUMIT

## Products Affected

- OPSUMIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Pregnancy |
| **Required Medical Information** | Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cardiologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ORFADIN

## Products Affected

- ORFADIN ORAL CAPSULE 20 MG
- ORFADIN ORAL SUSPENSION

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of hereditary tyrosinemia type 1 |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ORGOVYX

## Products Affected

- ORGOVYX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of advanced prostate cancer |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ORKAMBI

## Products Affected

- ORKAMBI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# OSPHENA

## Products Affected

- OSPHENA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following: A.) Undiagnosed abnormal genital bleeding, B.) Known or suspected estrogen-dependent neoplasia, C.) Active deep vein thrombosis (DVT), pulmonary embolism (PE), or a history of these conditions, D.) Active arterial thromboembolic disease (e.g. stroke, myocardial infarction) or a history of these conditions, or E.) Pregnancy |
| **Required Medical Information** | Diagnosis of one of the following A.) Moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause, or B.) Moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# OXANDROLONE

## Products Affected

- *oxandrolone oral*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following: A.) Known or suspected carcinoma of the prostate or breast in males, B.) Carcinoma of the breast in females with hypercalcemia, C.) Pregnancy, D.) Nephrosis or nephrotic phase of nephritis, E.) Hypercalcemia |
| **Required Medical Information** | Diagnosis of one of the following A.) Bone pain associated with osteoporosis, B.) Protein catabolism associated with chronic corticosteroid administration, or C.) Used as adjunctive therapy to promote weight gain after weight loss associated with one of the following 1.) Extensive surgery, 2.) Chronic infections, 3.) Severe trauma, or 4.) Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PANRETIN

## Products Affected

- PANRETIN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Patients with a known hypersensitivity to retinoids |
| **Required Medical Information** | Diagnosis of AIDS-related Kaposi's sarcoma with cutaneous lesions and systemic anti-Kaposi's Sarcoma therapy is not required (e.g., more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PEGYLATED INTERFERON

## Products Affected

- PEGASYS PROCLICK SUBCUTANEOUS SOLUTION 180 MCG/0.5ML
- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon, B.) Uncontrolled depression |
| **Required Medical Information** | Diagnosis of one of the following A.) Chronic hepatitis B infection, or B.) Chronic hepatitis C and required criteria will be applied consistent with current AASLD-IDSA guidance with compensated liver disease |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist |
| **Coverage Duration** | HBV: 12 months, HCV: based on current AASLD guidelines |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PEMAZYRE

## Products Affected

- PEMAZYRE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist, gastroenterologist, or hepatologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PHENYLBUTYRATE

## Products Affected

- *sodium phenylbutyrate oral powder 3 gm/tsp*
- *sodium phenylbutyrate oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Management of acute hyperammonemia |
| **Required Medical Information** | Diagnosis of urea cycle disorders involving deficiencies of carbamoylphosphate synthetase, ornithine transcarbamoylase, or argininosuccinic acid |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PIMECROLIMUS

## Products Affected

- *pimecrolimus*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of atopic dermatitis AND patient experienced an inadequate treatment response, intolerance, or contraindication to a generic topical steroid (i.e., betamethasone, fluocinonide, desoximetasone) |
| **Age Restrictions** | 2 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PIQRAY

## Products Affected

- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of hormone receptor (HR) positive, HER2-negative, PIK3CA-mutated, advanced or metastatic breast cancer AND must meet all of the following 1.) Used in combination with fulvestrant, AND 2.) Disease has progressed on or after an endocrine-based regimen, AND 3.) Patient is a male OR postmenopausal female |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# POMALYST

## Products Affected

- POMALYST

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Pregnancy |
| **Required Medical Information** | Diagnosis of one of the following A.) AIDS-related Kaposi sarcoma and patient has failure on highly active antiretroviral therapy (HAART), B.) Kaposi sarcoma in HIV-negative adults, or C.) Multiple myeloma and in combination with dexamethasone in adults who have received at least 2 prior therapies (including lenalidomide and a proteasome inhibitor) and have demonstrate disease progression on or within 60 days of completion of the last therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# POSACONAZOLE

## Products Affected

- *posaconazole*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Concomitant treatment with sirolimus, B.) Concomitant use of CYP3A4 substrates that prolong QT interval (pimozide, quinidine), C.) Concomitant use of HMG-CoA Reductase inhibitors primarily metabolized through CYP3A4, or D.) Concomitant use of ergot alkaloids |
| **Required Medical Information** | Diagnosis of one of the following A.) Patient is severely immunocompromised and requires prophylaxis of invasive aspergillosis due to high risk of infection, B.) Invasive aspergillosis, or C.) Patient is severely immunocompromised and requires prophylaxis of candidiasis due to high risk of infection |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PRILOSEC

## Products Affected

- PRILOSEC ORAL PACKET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with rilpivirine containing products |
| **Required Medical Information** | Diagnosis of one of the following: A.) Erosive esophagitis, B.) Gastroesophageal reflux disease, C.) Gastric ulcer, D.) Duodenal ulcer, E.) Helicobacter pylori gastrointestinal tract infection, or F.) Pathologic GI hypersecretory condition (including Zollinger-Ellison Syndrome) AND patient has had a failure, contraindication, or intolerance to Dexilant or a generic formulary proton pump inhibitor (i.e., lansoprazole, esomeprazole, omeprazole, pantoprazole) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PROMACTA

## Products Affected

- PROMACTA ORAL PACKET 12.5 MG, 25 MG
- PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Chronic idiopathic thrombocytopenic purpura (ITP), B.) Chronic hepatitis C infection associated thrombocytopenia, or C.) Severe aplastic anemia with insufficient response to immunosuppressive therapy or in combination with standard immunosuppressive therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PULMOZYME

## Products Affected

- PULMOZYME INHALATION SOLUTION 2.5 MG/2.5ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of cystic fibrosis (CF) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| **Coverage Duration** | 12 months |
| **Other Criteria** | B vs D determination required per CMS guidance |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PURIXAN

## Products Affected

- PURIXAN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Must meet all of the following 1.) Diagnosis of acute lymphocytic leukemia, 2.) Using in combination with methotrexate, 3.) Patient has tried/failed or has contraindication/intolerance to mercaptopurine tablets |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PYRIMETHAMINE

## Products Affected

- *pyrimethamine oral*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Documented megaloblastic anemia due to folate deficiency |
| **Required Medical Information** | Diagnosis of one of the following A.) Toxoplasmosis and treatment in combination with a sulfonamide, B.) Acute malaria and treatment in combination with a sulfonamide and the patient has had inadequate response/intolerance/contraindication to chloroquine or quinine, or C.) Chemoprophylaxis of malaria due to susceptible strains of plasmodia |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | 10 weeks |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# QINLOCK

## Products Affected

- QINLOCK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of advanced gastrointestinal stromal tumor (GIST) and patient has received prior treatment with 3 or more kinase inhibitors, including imatinib |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# QUININE SULFATE

## Products Affected

- *quinine sulfate oral*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following: A.) Prolongation of QT interval, B.) Glucose-6-phosphate dehydrogenase deficiency, C.) Myasthenia gravis, D.) Known hypersensitivity to mefloquine or quinidine, E.) Optic neuritis, F.) Diagnosis of Blackwater fever |
| **Required Medical Information** | Diagnosis of one of the following A.) uncomplicated Plasmodium falciparum malaria, B.) uncomplicated Plasmodium vivax malaria, or C.) babesiosis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 1 month |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# RAVICTI

## Products Affected

- RAVICTI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of urea cycle disorders |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# REGRANEX

## Products Affected

- REGRANEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Known neoplasm at the site of application |
| **Required Medical Information** | Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply |
| **Age Restrictions** | 16 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# REPATHA

## Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH), B.) homozygous familial hypercholesterolemia, C.) established cardiovascular disease and myocardial infarction prophylaxis, stroke prophylaxis, or coronary revascularization prophylaxis is required, or D.) clinical atherosclerotic cardiovascular disease (CVD) as defined as one of the following 1.) acute coronary syndrome, 2.) history of myocardial infarction, 3.) stable/unstable angina, 4.) coronary or other arterial revascularization, 5.) stroke, 6.) transient ischemic stroke (TIA), or 7.) peripheral arterial disease presumed to be atherosclerotic region |
| **Age Restrictions** | 10 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 2 months, Renewal: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# RETEVMO

## Products Affected

- RETEVMO ORAL CAPSULE 40 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in patients who require systemic therapy, B.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC), or C.) Advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and are refractory to radioactive iodine, if appropriate |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# REVLIMID

## Products Affected

- REVLIMID

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Pregnancy |
| **Required Medical Information** | Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# REZUROCK

## Products Affected

- REZUROCK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of chronic graft-vs-host disease in adult and pediatric patients at least 12 years of age after failure of at least 2 prior lines of systemic therapy. |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# RILUTEK

## Products Affected

- *riluzole*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of amyotrophic lateral sclerosis (ALS) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ROZLYTREK

## Products Affected

- ROZLYTREK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) ROS1-positive metastatic non-small cell lung cancer (NSCLC), or B.) 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 either progressed following treatment or have no satisfactory alternative therapy |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# RUBRACA

## Products Affected

- RUBRACA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Epithelial ovarian, fallopian tube, or primary peritoneal cancer with deleterious BRCA mutation (germline and/or somatic) as detected by an FDA-approved test and patient has been treated with 2 or more prior lines of chemotherapy, B.) Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, used as maintenance treatment, and patient is in complete or partial response to platinum-based chemotherapy, or C.) Deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer and patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# RYDAPT

## Products Affected

- RYDAPT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) treatment naive FLT3 mutation-positive acute myelogenous leukemia (AML) and must be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation therapy, or B.) systemic mastocytosis or mast cell leukemia |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SAPROPTERIN

## Products Affected

- *sapropterin dihydrochloride oral packet*
- *sapropterin dihydrochloride oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of hyperphenylalaninemia (HPA) caused by tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 2 months, Renewal: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SIGNIFOR

## Products Affected

- SIGNIFOR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of Cushing disease and patient has had inadequate response to or is not a candidate for surgery. For renewal: Documentation of a clinically meaningful reduction in 24-hour urinary free cortisol (UFC) levels or improvement in signs or symptoms of the disease |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 6 months, Reauthorization: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SILDENAFIL

## Products Affected

- *sildenafil citrate oral tablet 20 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Nitrate therapy, including intermittent use |
| **Required Medical Information** | Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cardiologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SIRTURO

## Products Affected

- SIRTURO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Must meet all of the following 1.) Diagnosis of pulmonary multidrug resistant tuberculosis (MDR-TB) and 2.) Used in combination with at least 3 other agents. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | 24 weeks |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SOLTAMOX

## Products Affected

- SOLTAMOX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Concomitant coumarin-type anticoagulant therapy, B.) history of thromboembolic disease such as DVT or PE |
| **Required Medical Information** | Diagnosis of breast cancer and documentation of inability to swallow tablet formulation |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SOMATULINE DEPOT

## Products Affected

- SOMATULINE DEPOT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Acromegaly and patient is not a candidate for surgery/radiotherapy or has had an inadequate response, B.) Carcinoid syndrome, or C.) Unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SOMAVERT

## Products Affected

- SOMAVERT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of acromegaly and patient has had an inadequate response to or is ineligible for surgery or radiation therapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SPRYCEL

## Products Affected

- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, B.) Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy, C.) Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy, D.) Newly diagnosed Ph+ ALL in combination with chemotherapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# STELARA

## Products Affected

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following: A.) Moderate to severely active Crohn disease and patient has trial and failure or intolerance or contraindication to Humira, B.) Moderate to severe plaque psoriasis and patient has trial and failure or intolerance or contraindication to Humira and Enbrel, C.) Active psoriatic arthritis and patient has trial and failure or intolerance or contraindication to Humira and Enbrel, or D.) Moderate to severe active ulcerative colitis and patient has trial and failure or intolerance or contraindication to Humira |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# STIVARGA

## Products Affected

- STIVARGA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Metastatic colorectal cancer in patients previously treated with fluoropyrimidine, oxaliplatin, and irinotecan containing chemotherapy, anti-VEGF therapy, and if RAS wild type, anti-EGFR therapy, B.) Liver carcinoma in patients previously treated with sorafenib, or C.) Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) after treatment with imatinib and sunitinib |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SUTENT

## Products Affected

- *sunitinib malate*
- SUTENT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Gastrointestinal stromal tumor after disease progression on or intolerance to imatinib, B.) Pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease, C.) Advanced renal cell carcinoma, or D.) Renal cell carcinoma and used as adjuvant therapy following nephrectomy in patients who are at high risk for recurrence |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SYMDEKO

## Products Affected

- SYMDEKO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of cystic fibrosis (CF) and must meet one of the following 1.) Patient is homozygous for the F508del mutation, or 2.) Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor verified by an FDA-cleared CF mutation test |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SYNAREL

## Products Affected

- SYNAREL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) pregnancy, B.) breastfeeding, C.) undiagnosed abnormal vaginal bleeding |
| **Required Medical Information** | Diagnosis of one of the following A.) Central precocious puberty, or B.) Endometriosis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# SYNRIBO

## Products Affected

- SYNRIBO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) and patient has tried and failed or has a contraindication or intolerance to at least 2 tyrosine kinase inhibitors |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TABLOID

## Products Affected

- TABLOID

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of acute myeloid leukemia (induction and consolidation therapy only) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TABRECTA

## Products Affected

- TABRECTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TAFINLAR

## Products Affected

- TAFINLAR ORAL CAPSULE 50 MG, 75 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid carcinoma with BRAF V600E mutation, in combination with trametinib and no satisfactory locoregional treatment options, B.) Metastatic non-small cell lung cancer with BRAF V600E mutation, in combination with trametinib OR in patients previously treated as monotherapy, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutation |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TAGRISSO

## Products Affected

- TAGRISSO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R mutation and used as first line therapy, B.) Metastatic non-small cell lung cancer with T790M EGFR mutation (as confirmed by an FDA-approved test) AND whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy, or C.) Non-small cell lung cancer (NSCLC) with tumor epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations (as confirmed by an FDA-approved test) AND patient requires adjuvant therapy after tumor resection |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TALZENNA

## Products Affected

- TALZENNA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TARGRETIN GEL

## Products Affected

- *bexarotene*
- TARGRETIN EXTERNAL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of primary cutaneous T-cell lymphoma (CTCL Stage 1A/1B) and patient had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) indicated for cutaneous manifestations of CTCL |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist/hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TASIGNA

## Products Affected

- TASIGNA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following: A.) Long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia |
| **Required Medical Information** | Diagnosis of one of the following A.) Newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML), B.) Chronic phase or accelerated phase Philadelphia chromosome-positive CML in a patient resistant or intolerant to prior therapy that included imatinib, or C.) Chronic phase Philadelphia chromosome-positive CML in a patient resistant or intolerant to prior tyrosine-kinase inhibitor therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TAZAROTENE

## Products Affected

- *tazarotene external cream*
- TAZORAC EXTERNAL GEL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Pregnancy |
| **Required Medical Information** | Diagnosis of one of the following A.) acne vulgaris and patient has trial with at least one generic topical acne product, or B.) stable moderate to severe plaque psoriasis with 20% or less body surface area involvement and patient has trial with at least one other topical psoriasis product (e.g., medium to high potency corticosteroid and/or vitamin D analogs) |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TAZVERIK

## Products Affected

- TAZVERIK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Metastatic or locally advanced epithelioid sarcoma in patients not eligible for complete resection, B.) Relapsed or refractory follicular lymphoma in patients whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, or C.) Relapsed or refractory follicular lymphoma in patients who have no satisfactory alternative treatment options |
| **Age Restrictions** | 16 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TEPMETKO

## Products Affected

- TEPMETKO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of metastatic non-small cell lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TESTOSTERONES

## Products Affected

- ANDRODERM TRANSDERMAL PATCH 24 HOUR
- *methyltestosterone oral*
- *testosterone transdermal gel 10 mg/act (2%), 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)*
- *testosterone transdermal solution*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following: A.) Carcinoma of the breast (males only), B.) Known or suspected carcinoma of the prostate, C.) Pregnancy |
| **Required Medical Information** | Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, B.) Inoperable metastatic breast cancer in women who are postmenopausal, C.) Primary hypogonadism, or D.) Delayed puberty. Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TETRABENAZINE

## Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Actively suicidal, B.) Untreated or inadequately treated depression, C.) Impaired hepatic function, D.) Concomitant use of monoamine oxidase inhibitors, E.) Concomitant use of reserpine or within 20 days of discontinuing reserpine |
| **Required Medical Information** | Diagnosis of chorea associated with Huntington's disease |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# THALOMID

## Products Affected

- THALOMID ORAL CAPSULE 100 MG, 150 MG, 200 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Pregnancy |
| **Required Medical Information** | Diagnosis of one of the following A.) Multiple myeloma that is newly diagnosed, or B.) Erythema nodosum leprosum (ENL) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or infectious disease specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TIBSOVO

## Products Affected

- TIBSOVO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test), or B.) adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test.), or C.) Newly diagnosed acute myeloid leukemia with susceptible isocitrate dehydrogenase-1 mutation AND meets one of the following 1.) Patient is 75 years of age or older, OR 2.) Patient has comorbidities that preclude intensive induction chemotherapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist, hematologist, gastroenterologist or hepatologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TOBI

## Products Affected

- TOBI PODHALER

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has suspected or confirmed Pseudomonas aeruginosa infection |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TOLVAPTAN

## Products Affected

- *tolvaptan*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following: A.) Diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD), B.) Urgent need to raise serum sodium acutely, C.) Inability to sense or appropriately respond to thirst, D.) Hypovolemic hyponatremia, E.) Concomitant use of strong CYP 3A Inhibitors (e.g. clarithromycin, ketoconazole, ritonavir), F.) Anuria |
| **Required Medical Information** | Diagnosis of clinically significant hypervolemic or euvolemic hyponatremia (serum sodium less than 125 mEq/L or less marks hyponatremia that is symptomatic and has resisted correction with fluid restriction), including in patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 1 month |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TOPICAL RETINOIDS

## Products Affected

- AVITA
- *tretinoin external*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of mild to moderate acne vulgaris |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TOREMIFENE

## Products Affected

- *toremifene citrate*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following: A.) Acquired or congenital long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia |
| **Required Medical Information** | Diagnosis of metastatic breast cancer and patient must have previous inadequate response or intolerance to tamoxifen |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TRELSTAR

## Products Affected

- TRELSTAR MIXJECT
  INTRAMUSCULAR SUSPENSION
  RECONSTITUTED 11.25 MG, 3.75 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of advanced prostate cancer and used in palliative treatment |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TRIENTINE

## Products Affected

- CLOVIQUE
- *trientine hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of Wilson's disease in patients that are intolerant to penicillamine |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TRIKAFTA

## Products Affected

- TRIKAFTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of cystic fibrosis (CF) and patient has at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene verified by an FDA-cleared CF mutation test |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TRUSELTIQ

## Products Affected

- TRUSELTIQ (100MG DAILY DOSE)
- TRUSELTIQ (125MG DAILY DOSE)
- TRUSELTIQ (50MG DAILY DOSE)
- TRUSELTIQ (75MG DAILY DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist, gastroenterologist or hepatologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TUKYSA

## Products Affected

- TUKYSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of advanced unresectable or metastatic HER2-positive breast cancer (including brain metastases) in patients who have received one or more prior anti-HER2-based regimens in the metastatic setting and drug is being used in combination with trastuzumab and capecitabine |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TURALIO

## Products Affected

- TURALIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# TYMLOS

## Products Affected

- TYMLOS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of postmenopausal osteoporosis and one of the following A.) osteoporotic fracture or multiple risk factors for fracture, or B.) previous trial of/or contraindication to bisphosphonate |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months (Maximum 24 month treatment per patient lifetime) |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# UKONIQ

## Products Affected

- UKONIQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen, or B.) Relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# UPTRAVI

## Products Affected

- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with strong CYP2C8 inhibitors (e.g., gemfibrozil) |
| **Required Medical Information** | Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cardiologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VALCHLOR

## Products Affected

- VALCHLOR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of cutaneous T-cell lymphoma (stage IA and IB mycosis fungoides-type) and patient has received prior skin-directed therapy (e.g. Topical corticosteroids, phototherapy, or topical nitrogen mustard) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VALTOCO

## Products Affected

- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE
- VALTOCO 20 MG DOSE
- VALTOCO 5 MG DOSE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Documentation of acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern. |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VARIZIG

## Products Affected

- VARIZIG INTRAMUSCULAR SOLUTION

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | History of hypersensitivity (including anaphylaxis or severe systemic reaction) to immune globulin or any component of the preparation |
| **Required Medical Information** | Diagnosis of post-exposure varicella (chickenpox) infection prophylaxis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VENCLEXTA

## Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with strong CYP3A inhibitor during the initial and titration phase in patients with CLL or SLL |
| **Required Medical Information** | Diagnosis of one of the following A.) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), or B.) Newly-diagnosed acute myeloid leukemia (AML) and used in combination with azacitidine, decitabine or low-dose cytarabine in patients 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VERQUVO

## Products Affected

- VERQUVO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Concomitant use of other soluble guanylate cyclase (sGC) stimulators, or B.) Pregnancy |
| **Required Medical Information** | Diagnosis of chronic heart failure (HF), NYHA Class II to IV and all of the following 1.) Left ventricular ejection fraction less than 45%, 2.) Previous hospitalization for HF within 6 months or outpatient IV diuretic treatment for HF within 3 months |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VERZENIO

## Products Affected

- VERZENIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of advanced or metastatic, HER2-negative, hormone receptor-positive breast cancer AND one of the following: A.) For postmenopausal women must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy and patient has trial and failure or contraindication to Ibrance or Kisqali, B.) For premenopausal or perimenopausal women must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy and patient has trial and failure or contraindication to Ibrance, C.) Used as monotherapy for treatment of disease progression following endocrine therapy and patient has already received at least one prior chemotherapy regimen of Ibrance or Kisqali, D.) For postmenopausal women used as initial endocrine-based treatment in combination with an aromatase inhibitor and patient has trial and failure or contraindication to Kisqali or Ibrance, E.) For premenopausal or perimenopausal women used as initial endocrine-based treatment in combination with an aromatase inhibitor and patient has trial and failure or contraindication to Kisqali, or F.) Used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor), for the adjuvant treatment of adult patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score of at least 20% as determined by an FDA-approved test |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VIGABATRIN

## Products Affected

- *vigabatrin*
- VIGADRONE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Infantile spasms, or B.) Refractory complex partial seizures and the drug is being used as adjunctive therapy in patients who have responded inadequately to several alternative treatments |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VITRAKVI

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of metastatic or surgically unresectable neurotrophic receptor tyrosine kinase (NTRK) gene fusion positive solid tumors and used in patients with unsatisfactory alternative treatments or who have progressed following treatment |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VIZIMPRO

## Products Affected

- VIZIMPRO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of metastatic non-small cell lung cancer with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VORICONAZOLE

## Products Affected

- *voriconazole intravenous*
- *voriconazole oral suspension reconstituted*
- *voriconazole oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Invasive aspergillosis, B.) Candidemia, C.) Esophageal Candidiasis, D.) Invasive candidiasis of the skin and abdomen, kidney, bladder wall, and wounds, or E.) Serious fungal infection due to Scedosporium apiospermum or Fusarium species |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | B vs D determination required per CMS guidance |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VOTRIENT

## Products Affected

- VOTRIENT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Advanced renal cell carcinoma, or B.) Advanced soft tissue sarcoma and patient received at least one prior chemotherapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# VYNDAMAX

## Products Affected

- VYNDAMAX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of wild type or hereditary transthyretin related familial amyloid cardiomyopathy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# WELIREG

## Products Affected

- WELIREG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XALKORI

## Products Affected

- XALKORI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive or ROS1-positive as detected by an FDA-approved test, or B.) Relapsed or refractory systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XELJANZ

## Products Affected

- XELJANZ
- XELJANZ XR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following: A.) Moderate to severe rheumatoid arthritis (RA) and patient has trial and failure or intolerance or contraindication to Humira and Enbrel, B.) Active psoriatic arthritis and patient has trial and failure or intolerance or contraindication to Humira and Enbrel, C.) Moderate to severe ulcerative colitis (UC) and patient has trial and failure or intolerance or contraindication to Humira, or D.) Polyarticular course juvenile idiopathic arthritis (pcJIA) and patient has trial and failure or intolerance or contraindication to Humira and Enbrel |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XGEVA

## Products Affected

- XGEVA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Hypocalcemia (calcium less than 8.0 mg/dL) |
| **Required Medical Information** | Diagnosis of one of the following A.) Bone metastases from a solid tumor and used for the prevention of skeletal related events, B.) Multiple myeloma and used for the prevention of skeletal related events, C.) Hypercalcemia of malignancy refractory to bisphosphonate therapy, or D.) Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XIFAXAN

## Products Affected

- XIFAXAN ORAL TABLET 550 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following: A.) Hepatic encephalopathy (HE) and used to reduce the risk of recurrence, or B.) Irritable bowel syndrome with diarrhea (IBS-D) AND the patient has not already received an initial 14-day course of treatment and two additional 14-day courses of treatment with the requested drug |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | HE: 6 months, IBS-D: 14 Days |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XOLAIR

## Products Affected

- XOLAIR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Chronic idiopathic urticaria in patients who remain symptomatic despite H1 antihistamine therapy, B.) Moderate to severe persistent asthma in patients with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids, or C.) Nasal polyps in patients with inadequate response to nasal corticosteroids |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XOSPATA

## Products Affected

- XOSPATA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XPOVIO

## Products Affected

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY)
- XPOVIO (60 MG ONCE WEEKLY)
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY)
- XPOVIO (80 MG TWICE WEEKLY)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Relapsed or refractory multiple myeloma being used in combination with dexamethasone in a patient who has received at least 4 prior therapies and is refractory to at least 2 proteasome inhibitors, at least 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody, B.) Relapsed or refractory diffuse large B-cell lymphoma (DLBCL, including from follicular lymphoma) in a patient who has received at least 2 lines of systemic therapy, or C.) Multiple myeloma being used in combination with bortezomib and dexamethasone in a patient who has received at least 1 prior therapy |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XTANDI

## Products Affected

- XTANDI ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Castration-resistant prostate cancer, or B.) Metastatic, castration-sensitive prostate cancer |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or urologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XURIDEN

## Products Affected

- XURIDEN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of hereditary orotic aciduria |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XYREM

## Products Affected

- XYREM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Concomitant treatment with sedative hypnotic agents, B.) Succinic semialdehyde dehydrogenase deficiency |
| **Required Medical Information** | Diagnosis of one of the following A.) narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to modafinil or armodafinil, or B.) cataplexy and narcolepsy |
| **Age Restrictions** | 7 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# XYWAV

## Products Affected

- XYWAV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Any of the following A.) Concomitant treatment with sedative hypnotic agents, B.) Succinic semialdehyde dehydrogenase deficiency |
| **Required Medical Information** | Diagnosis of one of the following A.) Narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to modafinil or armodafinil, B.) Cataplexy and narcolepsy, C.) Idiopathic hypersomnia in adults |
| **Age Restrictions** | Narcolepsy: 7 years of age and older. Idiopathic Hypersomnia: 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ZARXIO

## Products Affected

- ZARXIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Chemotherapy induced febrile neutropenia (prophylaxis), B.) Severe chronic neutropenia, C.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, or D.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ZEJULA

## Products Affected

- ZEJULA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and used as maintenance therapy in a patient who is in a complete or partial response to platinum-based chemotherapy, or B.) Advanced ovarian, fallopian tube, or primary peritoneal cancer and patient has been treated with 3 or more prior chemotherapy regimens, and cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA mutation, or genomic instability |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or gynecologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ZELBORAF

## Products Affected

- ZELBORAF

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Unresectable or metastatic melanoma and patient has positive BRAF-V600E mutation documented by an FDA-approved test, or B.) Erdheim-Chester disease and patient has documented BRAF V600 mutation |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ZEMDRI

## Products Affected

- ZEMDRI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of complicated urinary tract infection, including pyelonephritis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ZIEXTENZO

## Products Affected

- ZIEXTENZO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of chemotherapy induced febrile neutropenia (prophylaxis) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ZOLINZA

## Products Affected

- ZOLINZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of primary cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease on or following two systemic therapies (e.g., bexarotene, romidepsin, etc) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ZYDELIG

## Products Affected

- ZYDELIG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of one of the following A.) Chronic lymphocytic leukemia, used in combination with rituximab and patient has relapsed on at least one prior therapy, B.) Non-Hodgkins lymphoma (Follicular, B-Cell) and the patient has relapsed on at least two prior systemic therapies, or C.) Small lymphocytic lymphoma and the patient has relapsed on at least two prior systemic therapies |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# ZYKADIA

## Products Affected

- ZYKADIA ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# PART B VERSUS PART D

## Products Affected

- ABELCET INTRAVENOUS SUSPENSION 5 MG/ML
- *acetylcysteine inhalation solution 10 %, 20 %*
- *acyclovir sodium intravenous solution 50 mg/ml*
- *albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml*
- AMBISOME INTRAVENOUS SUSPENSION RECONSTITUTED 50 MG
- *amikacin sulfate injection solution 500 mg/2ml*
- AMINOSYN-PF INTRAVENOUS SOLUTION 7 %
- *amphotericin b intravenous solution reconstituted 50 mg*
- *ampicillin sodium injection solution reconstituted 1 gm, 125 mg*
- *ampicillin sodium intravenous solution reconstituted 10 gm*
- *ampicillin-sulbactam sodium injection solution reconstituted 1.5 (1-0.5) gm, 3 (2-1) gm*
- *ampicillin-sulbactam sodium intravenous solution reconstituted 15 (10-5) gm*
- *aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg*
- AZACTAM INJECTION SOLUTION RECONSTITUTED 2 GM
- *azathioprine oral tablet 50 mg*
- *azithromycin intravenous solution reconstituted 500 mg*
- *budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml*
- *calcitonin (salmon) nasal solution 200 unit/act*
- *calcitriol oral capsule 0.25 mcg, 0.5 mcg*
- *calcitriol oral solution 1 mcg/ml*
- *caspofungin acetate intravenous solution reconstituted 50 mg, 70 mg*
- *cefotetan disodium injection solution reconstituted 1 gm, 2 gm*
- *cefoxitin sodium intravenous solution reconstituted 1 gm, 10 gm, 2 gm*
- *cefuroxime sodium injection solution reconstituted 7.5 gm, 750 mg*
- *cefuroxime sodium intravenous solution reconstituted 1.5 gm*
- *chlorpromazine hcl oral concentrate 100 mg/ml, 30 mg/ml*
- *chlorpromazine hcl oral tablet 10 mg, 100 mg, 200 mg, 25 mg, 50 mg*
- *cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg*
- *ciprofloxacin in d5w intravenous solution 200 mg/100ml*
- *clindamycin phosphate injection solution 300 mg/2ml, 600 mg/4ml, 900 mg/6ml*
- CLINIMIX E/DEXTROSE (2.75/5) INTRAVENOUS SOLUTION 2.75 %
- CLINIMIX E/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX E/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX E/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX E/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- *colistimethate sodium (cba) injection solution reconstituted 150 mg*
- *cromolyn sodium inhalation nebulization solution 20 mg/2ml*
- *cyclophosphamide oral capsule 25 mg, 50 mg*

- *cyclophosphamide oral tablet 25 mg, 50 mg*
- *cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg*
- *cyclosporine modified oral solution 100 mg/ml*
- *cyclosporine oral capsule 100 mg, 25 mg*
- DEPO-PROVERA INTRAMUSCULAR SUSPENSION 400 MG/ML
- *dextrose intravenous solution 10 %, 5 %*
- *dextrose-nacl intravenous solution 10-0.2 %, 10-0.45 %, 2.5-0.45 %, 5-0.2 %, 5-0.45 %, 5-0.9 %*
- *diphtheria-tetanus toxoids dt intramuscular suspension 25-5 lfu/0.5ml*
- *doxercalciferol oral capsule 0.5 mcg, 1 mcg, 2.5 mcg*
- DOXY 100 INTRAVENOUS SOLUTION RECONSTITUTED 100 MG
- EMEND ORAL SUSPENSION RECONSTITUTED 125 MG/5ML
- ENGERIX-B INJECTION SUSPENSION 10 MCG/0.5ML, 20 MCG/ML
- ENVARSUS XR ORAL TABLET EXTENDED RELEASE 24 HOUR 0.75 MG, 1 MG, 4 MG
- ERAXIS INTRAVENOUS SOLUTION RECONSTITUTED 50 MG
- ERYTHROCIN LACTOBIONATE INTRAVENOUS SOLUTION RECONSTITUTED 500 MG
- *everolimus oral tablet 0.25 mg, 0.5 mg, 0.75 mg*
- *fluconazole in sodium chloride intravenous solution 200-0.9 mg/100ml-%, 400-0.9 mg/200ml-%*
- FREAMINE HBC INTRAVENOUS SOLUTION 6.9 %
- *furosemide injection solution 10 mg/ml, 10 mg/ml (4ml syringe)*
- GENGRAF ORAL CAPSULE 100 MG, 25 MG
- GENGRAF ORAL SOLUTION 100 MG/ML
- *gentamicin sulfate injection solution 40 mg/ml*
- *granisetron hcl oral tablet 1 mg*
- *heparin sodium (porcine) injection solution 1000 unit/ml, 10000 unit/ml, 20000 unit/ml, 5000 unit/ml*
- HEPATAMINE INTRAVENOUS SOLUTION 8 %
- *hydromorphone hcl pf injection solution 10 mg/ml, 50 mg/5ml*
- IMOVAX RABIES INTRAMUSCULAR INJECTABLE 2.5 UNIT/ML
- INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %
- *ipratropium bromide inhalation solution 0.02 %*
- *ipratropium-albuterol inhalation solution 0.5-2.5 (3) mg/3ml*
- ISOLYTE-P IN D5W INTRAVENOUS SOLUTION
- ISOLYTE-S INTRAVENOUS SOLUTION
- *kcl in dextrose-nacl intravenous solution 10-5-0.45 meq/l-%-%, 20-5-0.2 meq/l-%-%, 20-5-0.45 meq/l-%-%, 20-5-0.9 meq/l-%-%, 30-5-0.45 meq/l-%-%, 40-5-0.45 meq/l-%-%, 40-5-0.9 meq/l-%-%*
- *kcl-lactated ringers-d5w intravenous solution 20 meq/l*
- *levalbuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/0.5ml, 1.25 mg/3ml*
- *levocarnitine oral solution 1 gm/10ml*
- *levocarnitine oral tablet 330 mg*
- *levofloxacin in d5w intravenous solution 500 mg/100ml, 750 mg/150ml*
- *levofloxacin intravenous solution 25 mg/ml*
- *magnesium sulfate injection solution 50 %, 50 % (10ml syringe)*
- *methotrexate oral tablet 2.5 mg*
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
- *methotrexate sodium injection solution 50 mg/2ml*
- *metronidazole in nacl intravenous solution 5-0.79 mg/ml-%*

- *moxifloxacin hcl in nacl intravenous solution 400 mg/250ml*
- *mycophenolate mofetil oral capsule 250 mg*
- *mycophenolate mofetil oral suspension reconstituted 200 mg/ml*
- *mycophenolate mofetil oral tablet 500 mg*
- *mycophenolate sodium oral tablet delayed release 180 mg, 360 mg*
- *nafcillin sodium injection solution reconstituted 1 gm, 2 gm*
- *nafcillin sodium intravenous solution reconstituted 10 gm*
- NEPHRAMINE INTRAVENOUS SOLUTION 5.4 %
- NORMOSOL-M IN D5W INTRAVENOUS SOLUTION
- NUTRILIPID INTRAVENOUS EMULSION 20 %
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 2 GM/20ML
- *ondansetron hcl oral solution 4 mg/5ml*
- *ondansetron hcl oral tablet 24 mg, 4 mg, 8 mg*
- *ondansetron oral tablet dispersible 4 mg, 8 mg*
- *oxacillin sodium in dextrose intravenous solution 1 gm/50ml, 2 gm/50ml*
- *oxacillin sodium injection solution reconstituted 1 gm, 2 gm*
- *oxacillin sodium intravenous solution reconstituted 10 gm*
- *paricalcitol oral capsule 1 mcg, 2 mcg, 4 mcg*
- *penicillin g potassium injection solution reconstituted 20000000 unit*
- *penicillin g sodium injection solution reconstituted 5000000 unit*
- *pentamidine isethionate inhalation solution reconstituted 300 mg*
- *pentamidine isethionate injection solution reconstituted 300 mg*
- *perphenazine oral tablet 4 mg, 8 mg*
- PLASMA-LYTE 148 INTRAVENOUS SOLUTION
- PLASMA-LYTE A INTRAVENOUS SOLUTION
- *potassium chloride in dextrose intravenous solution 20-5 meq/l-%*
- *potassium chloride in nacl intravenous solution 20-0.45 meq/l-%, 20-0.9 meq/l-%, 40-0.9 meq/l-%*
- *potassium chloride intravenous solution 10 meq/100ml, 2 meq/ml, 2 meq/ml (20 ml), 20 meq/100ml, 40 meq/100ml*
- PREMASOL INTRAVENOUS SOLUTION 10 %
- PRIVIGEN INTRAVENOUS SOLUTION 20 GM/200ML
- PROCALAMINE INTRAVENOUS SOLUTION 3 %
- *prochlorperazine maleate oral tablet 10 mg, 5 mg*
- PROGRAF ORAL PACKET 0.2 MG, 1 MG
- PROSOL INTRAVENOUS SOLUTION 20 %
- RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED
- RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 10 MCG/ML (1ML SYRINGE), 40 MCG/ML, 5 MCG/0.5ML
- *rifampin intravenous solution reconstituted 600 mg*
- SANDIMMUNE ORAL SOLUTION 100 MG/ML
- *sirolimus oral solution 1 mg/ml*
- *sirolimus oral tablet 0.5 mg, 1 mg, 2 mg*
- *sodium chloride intravenous solution 0.45 %, 0.9 %, 3 %, 5 %*
- *tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg*
- TDVAX INTRAMUSCULAR SUSPENSION 2-2 LF/0.5ML
- TEFLARO INTRAVENOUS SOLUTION RECONSTITUTED 400 MG, 600 MG
- TENIVAC INTRAMUSCULAR INJECTABLE 5-2 LFU
- *tigecycline intravenous solution reconstituted 50 mg*

- *tobramycin inhalation nebulization solution 300 mg/5ml*
- *tobramycin sulfate injection solution 80 mg/2ml*
- TPN ELECTROLYTES INTRAVENOUS CONCENTRATE
- TRAVASOL INTRAVENOUS SOLUTION 10 %
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- VARUBI (180 MG DOSE) ORAL TABLET THERAPY PACK 2 X 90 MG
- XATMEP ORAL SOLUTION 2.5 MG/ML

## Details

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.

## Index of Drugs/Alphabetical Listing

**D**