

ABILIFY

Products Affected

- ABILIFY MAINTENA
- *aripiprazole oral solution*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of A) Major depressive disorder, Adjunctive treatment in patients receiving antidepressants. Patient needs to have a paid claim for an antidepressant drug (generic SSRI or SNRI or bupropion or mirtazapine). B) Schizophrenia, Bipolar Disorder, Psychomotor agitation or Autistic disorder: Patient needs to have a paid claim for one Atypical antipsychotic (olanzapine, quetiapine, risperidone, ziprasidone). |
| Age Restrictions | FDA Approved age specific diagnosis |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |

ACTIMMUNE

Products Affected

- ACTIMMUNE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of any medically accepted indications not otherwise excluded from Part D or atopic dermatitis |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ADAGEN

Products Affected

- ADAGEN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis for use. Adenosine deaminase deficiency - Severe combined immunodeficiency disease |
| Age Restrictions | Not approved for use in adults |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | If this medication is administered by a physician incident to a physicians visit, this would be covered by Medicare Part B |

ADCIRCA

Products Affected

- ADCIRCA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent use of organic nitrate or guanylate cyclase stimulators (includes intermittent use) |
| Required Medical Information | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization OR B) Doppler echocardiogram if patient is unable to undergo a right heart catheterization AND Patient has tried and had an insufficient response to at least one other PAH agent (e.g., sildenafil) therapy. |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | None |
| Coverage Duration | PAH: Initial: 6 months. Reauth: 12 months. |
| Other Criteria | PAH (Reauth): Documentation of positive clinical response to therapy. |

ADEMPAS

Products Affected

- ADEMPAS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension (WHO group I) AND diagnosis was confirmed by right heart catheterization OR Patient has a diagnosis of 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 AND female patients are enrolled in the ADEMPAS REMS program. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months - initial. 12 months - renewal |
| Other Criteria | None |

AFINITOR

Products Affected

- AFINITOR
- AFINITOR DISPERZ

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of advanced metastatic renal cell carcinoma and patient has failed therapy (disease progressed) with Sutent or Nexavar OR Diagnosis of pancreatic neuroendocrine tumors (pNET) that are unresectable, locally advanced, or metastatic OR Diagnosis of renal angiomyolipoma with tuberous sclerosis complex (TSC) and patient does not require immediate surgery OR Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer and patient is a postmenopausal woman and patient has failed treatment with Femara or Arimidex and the medication will be used in combination with Aromasin OR Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with TSC that requires therapeutic intervention but is not a candidate for curative surgical resection OR diagnosis of adult patients with progressive, well-differentiated, non-functional, neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin with unresectable, locally advanced, or metastatic disease OR diagnosis of tuberous sclerosis complex (TSC) associated partial seizures. |
| Age Restrictions | 18 years of age or older for RCC, pNET, and renal angiomyolipoma with TSC. 1 year of age or older for SEGA. 2 years of age or older for TSC associated partial seizures. |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ALDURAZYME

Products Affected

- ALDURAZYME

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Hurler or Hurler-Scheie form of Mucopolysaccharidosis I (MPS I) or Diagnosis of Scheie form of MPS I with moderate to severe symptoms. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ALECENSA

Products Affected

- ALECENSA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic anaplastic lymphoma kinase positive non-small cell lung cancer. Documentation of intolerance or disease progression following therapy with crizotinib |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ALIMTA

Products Affected

- ALIMTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ALIQOPA

Products Affected

- ALIQOPA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Follicular Lymphoma: Diagnosis of relapsed follicular lymphoma in patients who have received at least 2 prior systemic therapies |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ALUNBRIG

Products Affected

- ALUNBRIG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic, ALK positive non-small cell lung cancer and have progressed or are intolerant to Xalkori (crizotinib) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a oncologist |
| Coverage Duration | Plan year |
| Other Criteria | None |

AMPYRA

Products Affected

- AMPYRA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | History of seizure. Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute). |
| Required Medical Information | Diagnosis of multiple sclerosis. Patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting Ampyra. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | Initial - 3 months. Renewal - 12 months |
| Other Criteria | None |

APOKYN

Products Affected

- APOKYN SUBCUTANEOUS SOLUTION CARTRIDGE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Parkinson's Disease |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ATYPICAL ANTIPSYCHOTICS

Products Affected

- VRAYLAR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis AND inadequate response, intolerance, or contraindication to at least TWO formulary generic atypical antipsychotics agents (quetiapine, olanzapine, risperidone, ziprasidone, clozapine). |
| Age Restrictions | FDA approved age for specific product |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

AUBAGIO

Products Affected

- AUBAGIO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment. Current treatment with leflunomide. Patients who are pregnant or women of childbearing potential not using reliable contraception. |
| Required Medical Information | Diagnosis of relapsing forms of multiple sclerosis (e.g., relapsing-remitting MS or progressive-relapsing MS) OR patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | For renewal, patient has experienced an objective response to therapy (i.e., no or slowed progression of disease) |

AURYXIA

Products Affected

- AURYXIA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | For the management of hyperphosphatemia in patients with chronic kidney disease on dialysis |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

AUSTEDO

Products Affected

- AUSTEDO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | Any degree of hepatic impairment or hepatic disease, Patients with active suicidal ideation or who have untreated or inadequately treated depression |
| Required Medical Information | A. CHOREA ASSOCIATED WITH HUNTINGTONS DISEASE: Diagnosis of Chorea associated with Huntington's disease AND prescriber attestation that patient has NOT taken an MAOI in the past 14 days OR B. TARDIVE DYSKINESIA: Diagnosis of medication induced tardive Dyskinesia AND patient has a history of using a dopamine receptor antagonist |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a psychiatrist or neurologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

AVASTIN

Products Affected

- AVASTIN INTRAVENOUS SOLUTION
100 MG/4ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

BARACLUDE

Products Affected

- BARACLUDE ORAL SOLUTION
- *entecavir*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of chronic hepatitis B AND patient has evidence of viral replication AND Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) or histologically active disease AND patient is receiving anti-retroviral therapy if the patient has HIV co-infection |
| Age Restrictions | 2 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | For renewal, patient must be HBeAg negative OR HBeAg positive, but has not seroconverted OR HBeAg positive and seroconverted to anti-Hbe with detectable HBV DNA levels OR HbeAg positive and seroconverted to anti-Hbe with undetectable levels of HBV DNA levels for less than 12 months |

BAVENCIO

Products Affected

- BAVENCIO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Metastatic Merkel Cell Carcinoma OR Metastatic Urothelial Carcinoma, or locally advanced, in patients with disease progression during or following platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. |
| Age Restrictions | 12 years of age or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist. |
| Coverage Duration | 12 months |
| Other Criteria | None |

BELEODAQ

Products Affected

- BELEODAQ

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

BORTEZOMIB

Products Affected

- *bortezomib*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Multiple Myeloma OR Mantle Cell Lymphoma (MCL). For previously untreated Multiple Myeloma patients, bortezomib will be used in combination with melphalan and prednisone. For previously untreated MCL patients, bortezomib will be used in combination with rituximab, cyclophosphamide, doxorubin, and prednisone. |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist or hematologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

BOSULIF

Products Affected

- BOSULIF

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Philadelphia chromosome-positive (Ph+) CML with resistance, relapse, or inadequate response to prior therapy with one of the following tyrosine kinase inhibitors (TKI): Gleevec [imatinib] OR Tasigna [nilotinib] OR newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph + CML) |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |

BRIVIACT

Products Affected

- BRIVIACT

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of partial-onset seizures, member must have history of inadequate response, contraindication, or intolerance to levetiracetam prior to approval. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

CALQUENCE

Products Affected

- CALQUENCE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | MANTLE CELL LYMPHOMA (MCL) (1) Patient must have a diagnosis of MCL AND (2) Patient has tried one other therapy |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

CAPRELSA

Products Affected

- CAPRELSA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Congenital long QT syndrome |
| Required Medical Information | Diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

CAYSTON

Products Affected

- CAYSTON

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of cystic fibrosis is confirmed by appropriate diagnostic or genetic testing. Confirmation of <i>P. aeruginosa</i> in cultures of the airways. For continuation of therapy, a clinical reason to continue therapy, such as symptomatic improvement or pulmonary function tests have not deteriorated more than 10% from baseline. |
| Age Restrictions | 7 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | For renewal, Patient is benefiting from treatment (i.e., improvement in lung function [FEV1], decreased number of pulmonary exacerbations) |

CEREZYME

Products Affected

- CEREZYME INTRAVENOUS SOLUTION RECONSTITUTED 400 UNIT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis for use. Gaucher disease: Long-term enzyme replacement therapy for patients with a confirmed diagnosis of Type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | If this medication is administered by a physician incident to a physicians visit, this would be covered by Medicare Part B |

CHANTIX

Products Affected

- CHANTIX
- CHANTIX CONTINUING MONTH PAK
- CHANTIX STARTING MONTH PAK

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | List of previous therapies and documentation of response to previous smoking cessation therapies |
| Age Restrictions | Adults: 18 years and older. |
| Prescriber Restrictions | None |
| Coverage Duration | 3 months |
| Other Criteria | Requests for Chantix will be approved for smoking cessation treatment in patients who have documented failure with nicotine replacement therapy AND who have had failure on a therapeutic course of Bupropion (7-9 weeks) or have a contraindication to its use. Patients should be treated with CHANTIX for 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with CHANTIX is recommended to further increase the likelihood of long-term abstinence. Patients who do not succeed in stopping smoking during 12 weeks of initial therapy, or who relapse after treatment, should be encouraged to make another attempt once factors contributing to the failed attempt have been identified and addressed |

CINRYZE

Products Affected

- CINRYZE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | History of life-threatening immediate hypersensitivity reactions, including anaphylaxis to the product. |
| Required Medical Information | Diagnosis of hereditary angioedema AND Medication will be used for routine prophylaxis against angioedema. |
| Age Restrictions | None |
| Prescriber Restrictions | prescribed or overseen by a hematologist or immunologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

COLISTIN

Products Affected

- *colistimethate sodium (cba)*
- *colistimethate sodium injection*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

COMETRIQ

Products Affected

- COMETRIQ (100 MG DAILY DOSE)
- COMETRIQ (140 MG DAILY DOSE)
- COMETRIQ (60 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Gastrointestinal perforation. Fistula. Severe hemorrhage. |
| Required Medical Information | Diagnosis of progressive, metastatic medullary thyroid cancer |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

COPAXONE

Products Affected

- *glatiramer acetate*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of relapsing-remitting multiple sclerosis OR diagnosis of first clinical episode with MRI features consistent with multiple sclerosis |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | For renewal, patient has no or slowed disease progression |

CORLANOR

Products Affected

- CORLANOR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Decompensated acute heart failure, hypotension (i.e. blood pressure less than 90/50 mmHg), sick sinus syndrome or sinoatrial block or 3rd degree AV block (unless a functioning demand pacemaker is present), or bradycardia (i.e., resting heart rate less than 60 bpm prior to treatment). |
| Required Medical Information | Patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction 35% or less, who are in sinus rhythm with resting heart rate 70 beats per minute or more and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 Months |
| Other Criteria | None |

COTELLIC

Products Affected

- COTELLIC

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of unresectable OR metastatic malignant melanoma with BRAF V600E OR V600K mutation. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

CYSTARAN

Products Affected

- CYSTARAN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Patient has a diagnosis of cystinosis AND Patient has corneal cystine crystal accumulation |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

DICLOFENAC TOPICAL

Products Affected

- *diclofenac sodium transdermal gel*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Voltaren 1%: Diagnosis of osteoarthritis, diclofenac 3% gel: Diagnosis of actinic keratosis |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

DRONABINOL

Products Affected

- *dronabinol*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | A. The diagnosis is documented as anorexia associated with weight loss in a patient with AIDS a. AND the patient has had an involuntary weight loss of greater than 10% of pre-illness baseline body weight or a body mass index (BMI) less than 20kg/m ² in the absence of a concurrent illness or medical condition other than HIV that may cause weight loss b. AND the patient has failed to respond to a 30-day drug regimen of megestrol (Megace) c. AND if the patient has received previous dronabinol therapy, he/she must show a positive response to therapy by maintaining or increasing their initial weight and/or muscle mass before initiating dronabinol therapy. B. The diagnosis is documented as nausea and vomiting associated with cancer chemotherapy in a cancer patient a. AND the patient is receiving a chemotherapy or radiation regimen b. AND the patient has had a full trial and failure through at least one cycle of chemotherapy with IV ondansetron AND at least one of the following oral anti-emetic agents: metoclopramide, promethazine, prochlorperazine, meclizine, trimethobenzamide, oral 5-HT ₃ receptor antagonists e. AND if the patient has received previous dronabinol therapy, he/she must show a positive response by showing a reduced incidence of emesis and/or nausea. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | B vs D coverage determination per CMS guidelines |

ELITEK

Products Affected

- ELITEK

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | None |

EMCYT

Products Affected

- EMCYT

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | Approve for continuation of prior therapy |

ENDARI

Products Affected

- ENDARI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of acute sickle cell disease AND patient must have trial history of Hydroxyurea. Otherwise Endari requires documentation of (1) history of inadequate treatment with Hydroxyurea OR (2) history of adverse event with Hydroxyurea OR (3) Hydroxyurea is contraindicated. |
| Age Restrictions | 5 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ENTRESTO

Products Affected

- ENTRESTO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | History of angioedema related to previous ACE inhibitor or ARB therapy, concomitant use or use within 36 hours of ACE inhibitors, concomitant use of aliskiren in patients with diabetes |
| Required Medical Information | Statement of diagnosis indicating Heart Failure (NYHA Class II through IV). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |

EPOGEN

Products Affected

- EPOGEN INJECTION SOLUTION UNIT/ML, 3000 UNIT/ML, 4000
10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Available for coverage under PART B |
| Required Medical Information | For use in an anemic patient prior to surgery. For other indications, all of the following criteria are required: 1) The pretreatment Hgb is less than or equal to 10 g/dL for initial authorization. 2) Dose reduction or interruption if hemoglobin exceeds 10g/dL in patients with CKD not on dialysis (adult, cancer), 11 g/dL in patients with CKD on dialysis, or 12 g/dL in pediatric CKD patients. 3) Once on therapy for 12 weeks, the hemoglobin must increase at least 1 g/dL in response to epoetin alfa. AND 4) documented to have previously received at least a one day supply of preferred formulary alternative PROCRT or have a contraindication to PROCRT |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 3 months |
| Other Criteria | None |

ERAXIS

Products Affected

- ERAXIS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis for use |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 6 weeks |
| Other Criteria | The patient will need to have tried and failed fluconazole and oral Vfend. Eraxis has not been studied in endocarditis, osteomyelitis, and meningitis due to Candida and has not been studied in sufficient numbers of neutropenic patients to determine efficacy in this group. |

ERIVEDGE

Products Affected

- ERIVEDGE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic basal cell carcinoma OR Diagnosis of locally advanced basal cell carcinoma that has recurred following surgery or when the patient is not a candidate for surgery and radiation |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ERLEADA

Products Affected

- ERLEADA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of nonmetastatic, 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 | Plan Year |
| Other Criteria | None |

ERWINAZE

Products Affected

- ERWINAZE INJECTION

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist or hematologist |
| Coverage Duration | Plan Year |
| Other Criteria | Patient has developed hypersensitivity to E. coli-derived asparaginase. |

ESBRIET

Products Affected

- ESBRIET

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Appropriate diagnosis (idiopathic pulmonary fibrosis [IPF]) and monitoring (hepatic function/LFTs) |
| Age Restrictions | None |
| Prescriber Restrictions | Prescriber must be a pulmonologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ESRD THERAPY

Products Affected

- PROCRIT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Pretreatment hemoglobin levels of less than 10g/dL. Dose reduction or interruption if hemoglobin exceeds 10 g/dL (CKD not on dialysis-adult, cancer), 11 g/dL (CKD on dialysis), 12 g/dL (pediatric CKD) in addition to supporting statement of diagnosis from physician. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 3 months |
| Other Criteria | None |

EXJADE

Products Affected

- EXJADE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Medical documentation of FDA approved diagnosis, serum ferritin levels, and serum creatinine. |
| Age Restrictions | Covered for those 2 years of age and older with chronic iron overload due to blood transfusions |
| Prescriber Restrictions | Hematologist |
| Coverage Duration | 3 months |
| Other Criteria | None |

FABRAZYME

Products Affected

- FABRAZYME

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis confirmed with an enzyme assay measuring a deficiency of alpha-galactosidase enzyme activity or DNA testing. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | If this medication is administered by a physician incident to a physicians visit, this would be covered by Medicare Part B |

FARESTON

Products Affected

- FARESTON

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis: Must have previous inadequate response or intolerance to tamoxifen. For reauth: must have chart documentation from prescriber indicating improvement in condition. |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist or hematologist |
| Coverage Duration | 6 months |
| Other Criteria | None |

FARYDAK

Products Affected

- FARYDAK

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Multiple Myeloma (MM) Used in combination with both of the following: Velcade (bortezomib) and dexamethasone. Patient has received at least two prior treatment regimens which included both of the following: Velcade (bortezomib) and an immunomodulatory agent [e.g., Revlimid (lenalidomide), Thalomid (thalidomide)]. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist/hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |

FENTANYL ORAL

Products Affected

- *fentanyl citrate buccal*
- LAZANDA
- SUBSYS SUBLINGUAL LIQUID 100 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Management of acute or post-operative pain, including headache/migraine, dental pain, or use in the emergency room. Opioid non-tolerant patients. |
| Required Medical Information | Patient meets the following: A) Diagnosis of cancer and use is for breakthrough cancer pain, B) Must have documented history of at least two of the following alts: HYDROMORPHONE, APAP/CODEINE, OXYCODONE/APAP, OXYCODONE, HYDROCODONE/APAP) being ineffective, not tolerated, or contraindicated, C) prescriber is registered in the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy Access program |
| Age Restrictions | 18 years of age or older for Lazanda and Subsys mucosal, 16 years of age or older for all others |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

FENTANYL PATCH

Products Affected

- *fentanyl*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Management of acute or post-operative pain. Opioid non-tolerant patients. |
| Required Medical Information | Patient is opioid tolerant (taking for one week or longer at least 60mg of morphine or equivalent daily) AND has tried one extended release oral opioid or is unable to take extended release oral opioids secondary to allergy, adverse events, swallowing difficulty, or uncontrollable nausea/vomiting. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |

FIRAZYR

Products Affected

- FIRAZYR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of hereditary angioedema AND medication will be used for the treatment of acute attacks. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | prescribed or overseen by a hematologist or immunologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

FORTEO

Products Affected

- FORTEO SUBCUTANEOUS SOLUTION 600 MCG/2.4ML

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Documentation of past therapies and outcomes (failure defined as loss of BMD OR has fragility fracture(s) after a treatment with a first-line pharmacologic treatment bisphosphonate, Evista, or calcitonin). Diagnosis for use. Fracture history. Documentation of high risk for fracture for postmenopausal women, high risk defined with the presence of two of the following: low BMD scores (T-score less than or equal to -2.5 at the spine or hip or both), age greater than 70, or positive family history for osteoporosis in a 1st degree relative. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 2 years |
| Other Criteria | For postmenopausal women with osteoporosis at high risk for fracture and men with primary or hypogonadal osteoporosis, require documentation of trial and failure on at least one first-line therapy (alendronate, Evista, Atelvia, or Prolia) or documentation of intolerance to at least two first-line therapies. For patients with glucocorticoid induced osteoporosis, require documentation of trial and failure to either alendronate or Atelvia or documented intolerance to both alendronate and Atelvia |

GILOTRIF

Products Affected

- GILOTRIF

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Supporting statement of diagnosis of metastatic non-small cell lung cancer (NSCLC) from the physician in patients with EGFR exon 19 deletions or exon 21 (L858R) substitution as detected by an FDA-approved test OR Treatment of previously treated metastatic squamous cell NSCLC that has progressed following platinum-based chemotherapy |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

GLEEVEC

Products Affected

- *imatinib mesylate*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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 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, G) aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutation or with c-KIT mutational status unknown |
| Age Restrictions | 1 year of age or older - newly diagnosed CML in the chronic phase or newly diagnosed, Ph+ ALL. 18 years of age or older for other indications. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

GONADOTROPIN

Products Affected

- *chorionic gonadotropin intramuscular*
- NOVAREL INTRAMUSCULAR SOLUTION RECONSTITUTED 5000 UNIT

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Fertility indications in females are excluded. |
| Required Medical Information | Diagnosis of Hypogonadotropic hypogonadism or Prepubertal cryptorchidism |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

GROWTH HORMONE

Products Affected

- NORDITROPIN FLEXPRO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

GUANFACINE ER

Products Affected

- *guanfacine hcl er*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of attention deficit hyperactivity disorder. |
| Age Restrictions | Approved for patients over 6 years of age but under 18 years of age. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HALAVEN

Products Affected

- HALAVEN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | A documented diagnosis of metastatic breast cancer AND documented prior therapy with both an anthracycline (i.e., daunorubicin, bleomycin) and a taxane (i.e., paclitaxel, docetaxel) OR documented diagnosis of unresectable or metastatic liposarcoma who have received a prior anthracycline (i.e., daunorubicin, bleomycin). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist. |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HEPATITIS C

Products Affected

- EPCLUSA
- MAVYRET
- ZEPATIER

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Must submit documentation of chronic hepatitis C genotype (confirmed by HCV RNA level within the last 6 months). Must submit laboratory results within 6 weeks of initiating therapy including: 1) CBC w Platelets, 2) AST/ALT, 3)Total Bilirubin, 4)Serum Albumin, 5)PT/INR, 6)Serum Creatinine, and 7)GFR. FOR GENOTYPES 1 and 4: Must include subtype, trail/failure, contraindication to, or intolerance to Zepatier or Mavyret prior to approval of Epclusa. |
| Age Restrictions | Patient must be age 18. |
| Prescriber Restrictions | Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist |
| Coverage Duration | Duration of approval per AASLD Guidelines |
| Other Criteria | None |

HETLIOZ

Products Affected

- HETLIOZ

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Non-24-hour-sleep-wake disorder (Non-24) AND patient has documented blindness |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months (initial), 12 months (renewal) |
| Other Criteria | None |

HEXALEN

Products Affected

- HEXALEN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe bone marrow depression-indicated by CBC. Severe neurologic toxicity-Seizure. |
| Required Medical Information | Diagnosis of persistent or recurrent ovarian cancer AND the medication will be used as palliative treatment AND the medication will be used as a single agent AND the medication will be used following first-line therapy with a cisplatin and/or alkylating agent-based combination. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HRM

Products Affected

- NATPARA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Verify the medication is being used for an FDA-approved diagnosis |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HRM - ANALGESICS

Products Affected

- ASCOMP-CODEINE
- butalbital-apap-caff-cod
- indomethacin er
- indomethacin oral
- ketorolac tromethamine injection solution 15 mg/ml, 30 mg/ml
- ketorolac tromethamine intramuscular solution 60 mg/2ml
- ketorolac tromethamine oral
- meperidine hcl injection solution 100 mg/ml, 25 mg/ml, 50 mg/ml
- meperidine hcl oral
- pentazocine-naloxone hcl

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is 1) being prescribed for an FDA-approved indication AND 2) If formulary non HRM alternatives considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) (ALTERNATIVES for the following diagnoses include a) ACUTE PAIN/INFLAMMATION: acetaminophen/codeine, tramadol, tramadol/APAP, morphine sulfate, hydrocodone/APAP, oxycodone, oxycodone/APAP, etodolac, diflunisal, ibuprofen, ketoprofen, nabumetone, sulindac, meloxicam, naproxen. b) OSTEOARTHRITIS: etodolac, diflunisal, fenoprofen, ibuprofen, ketoprofen, nabumetone, sulindac, meloxicam, naproxen. c) GOUT: etodolac, ketoprofen, meloxicam, sulindac. d) HEADACHE: ibuprofen, naproxen) AND 3) the prescribing physician attests to the medical necessity for using this high risk medication, AND 4) intent to monitor for side effects, AND 5) anticipated treatment course/duration |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Not covered for members if drug is available for hospice program drug benefit. |

HRM - ANTI-ARRHYTHMICS

Products Affected

- DIGITEK ORAL TABLET 250 MCG
- DIGOX ORAL TABLET 250 MCG
- *digoxin injection*
- *digoxin oral solution*
- *digoxin oral tablet 250 mcg*
- *disopyramide phosphate oral*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives (DIGOXIN: Digoxin 0.125mg dose, propranolol or sotalol for atrial fibrillation, DISOPYRAMIDE: dofetilide, amiodarone, propafenone, mexiletine, multaq) considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) AND the prescribing physician attests to the medical necessity for using this high risk medication, AND Monitoring plan for adverse side effects, AND anticipated treatment course/duration. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HRM - ANTIDEPRESSANTS

Products Affected

- *amitriptyline hcl oral*
- *amoxapine*
- *clomipramine hcl oral*
- *desipramine hcl oral*
- *doxepin hcl oral*
- *imipramine hcl oral*
- *imipramine pamoate*
- *nortriptyline hcl oral*
- *protriptyline hcl*
- *trimipramine maleate oral*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Documentation of prescriber attestation that benefit outweighs risk of drugs found to be high risk medications for beneficiaries age 65 and older. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HRM - ANTIEMETIC DRUGS

Products Affected

- *hydroxyzine hcl intramuscular*
- *hydroxyzine hcl oral syrup*
- *hydroxyzine hcl oral tablet*
- *hydroxyzine pamoate oral*
- *promethazine hcl oral syrup*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal suppository 50 mg*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Documentation of prescriber attestation that benefit outweighs risk of drugs found to be high risk medications for beneficiaries age 65 and older. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Must try and fail, have contraindication or intolerance to at least 2 non-HRM alternatives: Nausea/Vomiting: granisetron, ondansetron Allergic Reactions: cetirizine solution, desloratadine, levocetirizine. Part D coverage is not allowed if a hospice program drug benefit is available for the drug. |

HRM - ANTIHISTAMINES

Products Affected

- *cyproheptadine hcl oral*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives (cetirizine syrup, desloratadine, levocetirizine) considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) AND the prescribing physician attests to the medical necessity for using this high risk medication, AND intent to monitor for side effects, AND anticipated treatment course/duration |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | NON HRM formulary alternatives are desloratadine, levocetirizine |

HRM - ANTIHYPERTENSIVE AGENTS

Products Affected

- *methyldopa oral*
- *methyldopa-hydrochlorothiazide*
- *methyldopate hcl*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives (Low dose thiazide or a second generation calcium channel blocker OR ACE inhibitor, ARB, beta-blocker or combination product based on specific chronic conditions) considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) AND the prescribing physician attests to the medical necessity for using this high risk medication, AND intent to monitor for side effects, AND anticipated treatment course/duration |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Low dose thiazide or a second generation calcium channel blocker OR ACE inhibitor, ARB, beta-blocker or combination product based on specific chronic conditions |

HRM - ANTIPARKINSON AGENTS

Products Affected

- *benztropine mesylate injection*
- *benztropine mesylate oral*
- *trihexyphenidyl hcl*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Documentation of prescriber attestation that benefit outweighs risk of drugs found to be high risk medications for beneficiaries age 65 and older. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HRM - ANTIPSYCHOTICS

Products Affected

- *thioridazine hcl oral*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives (haloperidol, quetiapine, risperidone, aripiprazole, asenapine, iloperidone, lurasidone, olanzapine, paliperidone, ziprasidone) considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) AND the prescribing physician attests to the medical necessity for using this high risk medication, AND intent to monitor for side effects, AND anticipated treatment course/duration |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Applies to New Starts only. Must try/fail, have contraindication or intolerance to at least 2 of the following: haloperidol, quetiapine, risperidone, aripiprazole, asenapine, iloperidone, lurasidone, olanzapine, paliperidone, ziprasidone |

HRM - BARBITURATES

Products Affected

- *phenobarbital oral elixir*
- *phenobarbital oral tablet*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is 1) being prescribed for an FDA-approved indication AND 2) If formulary non HRM alternatives considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) (Alternatives for the following diagnoses include a) ANXIETY: citalopram, escitalopram, fluvoxamine, sertraline, duloxetine, venlafaxine, buspirone. b) INSOMNIA: ramelteon (8 mg/d), AND low dose trazodone) AND 3) the prescribing physician attests to the medical necessity for using this high risk medication, AND 4) Prescriber attests to the intent to monitor for side effects, AND 5) anticipated treatment course/duration. For treatment of seizure diagnosis, requests will be automatically approved. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HRM - ONCOLOGY

Products Affected

- *megestrol acetate oral suspension 40 mg/ml, 625 mg/5ml*
- *megestrol acetate oral tablet*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives for diagnosis of cachexia secondary to chronic illness (dronabinol, oxandrolone) considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) AND the prescribing physician attests to the medical necessity for using this high risk medication, AND intent to monitor for side effects, AND anticipated treatment course/duration. For treatment of cancer related diagnosis or endometrial hyperplasia, or endometriosis, requests will be automatically approved. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Applies to New Starts only |

HRM - ORAL AND TRANSDERMAL ESTROGENS AND PROGESTINS

Products Affected

- *estradiol oral*
- *estradiol transdermal patch weekly*
- *estradiol-norethindrone acet*
- *estropipate oral tablet 0.75 mg*
- JINTELI
- MENEST ORAL TABLET 0.3 MG, 0.625 MG, 1.25 MG
- MIMVEY
- MIMVEY LO
- PREMARIN INJECTION
- PREMARIN ORAL
- PREMPHASE
- PREMPRO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) AND the prescribing physician attests to the medical necessity for using this high risk medication, AND intent to monitor for side effects, AND anticipated treatment course/duration. Non-HRM Alternatives: IF BEING USED TO TREAT Bone Density issues must try 2 of the safer alternatives: alendronate, risedronate, ibandronate, raloxifene OR (zoledronic acid for bed-bound patients or for post-hip fracture). IF BEING USED TO TREAT Post-menopausal symptoms must try 2 of the safer alternatives: citalopram, fluoxetine, sertraline, venlafaxine, Premarin Vaginal Cream. IF BEING USED TO TREAT Vaginal Symptoms must try vaginal estrogen cream |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Bone Density: alendronate, risedronate, ibandronate, raloxifene (zoledronic acid for bed-bound patients or for post-hip fracture). Vaginal Symptoms: |

| PA Criteria | Criteria Details |
|--------------------|-------------------------|
| | vaginal estrogen cream |

HRM - SEDATIVE HYPNOTIC AGENTS

Products Affected

- *zaleplon*
- *zolpidem tartrate oral*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives (Rozerem (8 mg/d), Silenor (less than or equal to 6mg/d)) considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) AND the prescribing physician attests to the medical necessity for using this high risk medication, AND intent to monitor for side effects, AND anticipated treatment course/duration |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | ramelteon (8 mg/d), low-dose doxepin (less than or equal to 6mg/d) |

HRM - SKELETAL MUSCLE RELAXANTS

Products Affected

- *chlorzoxazone oral tablet 500 mg*
- *cyclobenzaprine hcl oral*
- *metaxalone oral tablet 800 mg*
- *methocarbamol injection solution 1000 mg/10ml*
- *methocarbamol oral*
- *orphenadrine citrate er*
- *orphenadrine citrate injection*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is being prescribed for an FDA-approved indication AND the prescribing physician attests that the benefit outweighs risk of therapy, AND intent to monitor for side effects, AND anticipated treatment course/duration. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HRM - UTI ANTIBACTERIALS

Products Affected

- *nitrofurantoin macrocrystal oral*
- *nitrofurantoin oral suspension*
- *nitrofurantoin monohyd macro*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives (Non-HRM alternatives: ciprofloxacin, levofloxacin, sulfamethoxazole/trimethoprim) considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) AND the prescribing physician attests to the medical necessity for using this high risk medication, AND intent to monitor for side effects, AND anticipated treatment course/duration |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HRM-INCONTINENCE

Products Affected

- *oxybutynin chloride er*
- *oxybutynin chloride oral*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | The drug is being prescribed for an FDA-approved indication AND the prescribing physician attests that the benefit outweighs risk of therapy, AND intent to monitor for side effects, AND anticipated treatment course/duration. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

HYDROXYPROGESTERONE CAPROATE

Products Affected

- *hydroxyprogesterone caproate intramuscular solution*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Breast, cervical, hepatocellular, uterine, or vaginal cancers, hepatic or thromboembolic disease, jaundice, or vaginal bleeding |
| Required Medical Information | Supporting statement of diagnosis from physician |
| Age Restrictions | 16 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 21 weeks |
| Other Criteria | None |

HYSINGLA

Products Affected

- HYSINGLA ER

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Must have severe pain requiring around-the-clock long term opioid, AND all of these: 1- ONE of the following formulary opioid options, hydrocodone IR, oxycodone IR, morphine IR, hydromorphone IR, OR methadone are ineffective, not tolerated, or inadequate for controlling pain AND fentanyl patches are ineffective, not tolerated, or inadequate for controlling pain 2-Must discontinue all other around-the-clock opioids when initiated 3-Care plan/agreement for opioid therapy has been established 4-Pt advised of risks and provides informed consent for chronic opioid therapy 5-Pt assessed for all these (i)pain severity (ii)suitability of non-opioids (iii)physical & emotional functional status (iv)risk of or current aberrant drug behavior 5- Prescriber will attest to intent of monitoring for signs of misuse, abuse and addiction during therapy AND ONE of these: A-Opioid naive/non-tolerant must start formulary IR hydrocodone/APAP at 10mg twice day for 7 days before titrating up OR B-Opioid tolerant, receiving one of these doses per day for at least 1 week: 60mg oral morphine, 25mcg transdermal fentanyl/hr, 30mg oral oxycodone, 8mg oral hydromorphone |
| Age Restrictions | Adults: 18 years and older. |
| Prescriber Restrictions | Prescriber is knowledgeable in the use of potent opioids for the management of chronic pain |
| Coverage Duration | 90 days |
| Other Criteria | None |

IBRANCE

Products Affected

- IBRANCE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Appropriate diagnosis (used in combination with an aromatase inhibitor for the treatment of postmenopausal women with hormone receptor HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer OR diagnosis of the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with fulvestrant in women with disease progression following endocrine therapy.) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist. |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ICLUSIG

Products Affected

- ICLUSIG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of 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 OR Diagnosis of 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 | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

IDHIFA

Products Affected

- IDHIFA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase 2 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 | Plan Year |
| Other Criteria | None |

IMBRUVICA

Products Affected

- IMBRUVICA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

IMFINZI

Products Affected

- IMFINZI

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of locally advanced or metastatic urothelial carcinoma. Patients must have progressed on or following platinum-containing chemotherapy, OR 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 a oncologist |
| Coverage Duration | Plan year |
| Other Criteria | None |

INCRELEX

Products Affected

- INCRELEX

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Increlex is contraindicated in patients with allergies to mecasermin or any component of the Increlex formulation, for growth promotion in patients with closed epiphyses, for IV administration, in patients with active or suspected neoplasia. Increlex should be discontinued if neoplasia develops while on therapy. |
| Required Medical Information | Increlex (mecasermin [rDNA origin] injection) is indicated for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Child has one of the following conditions: Severe primary IGF-1 deficiency, OR Growth hormone gene deletion with developed neutralizing antibodies to growth hormone, OR Genetic mutation of GH receptor (i.e. Laron Syndrome), AND Child has severe growth retardation with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex, AND Child with IGF-1 level greater than or equal to 3 standard deviations below normal based on lab reference range for age and sex, AND Child with normal or elevated growth hormone (GH) levels based on at least one growth hormone stimulation test, AND Evidence of open epiphyses |
| Age Restrictions | None |
| Prescriber Restrictions | Pediatric or Endocrinologist |
| Coverage Duration | 6 months |
| Other Criteria | None |

INHALED TOBRAMYCIN

Products Affected

- TOBI PODHALER

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of cystic fibrosis AND patient has evidence of P. aeruginosa in the lungs |
| Age Restrictions | 6 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | For renewal, Patient is benefiting from treatment (i.e. improvement in lung function [FEV1], decreased number of pulmonary exacerbations). |

INJECTABLE ANTICOAGULANT

Products Affected

- *fondaparinux sodium* UNIT/0.5ML, 15000 UNIT/0.6ML, 18000
- FRAGMIN SUBCUTANEOUS UNT/0.72ML, 2500 UNIT/0.2ML, 5000
SOLUTION 10000 UNIT/ML, 12500 UNIT/0.2ML

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Cancer-related DVT: 5 months, All other covered indications: 1 month |
| Other Criteria | None |

INLYTA

Products Affected

- INLYTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of advanced renal cell carcinoma AND patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens) |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

INTRAROSA

Products Affected

- INTRAROSA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | Vaginal bleeding or dysfunctional uterine bleeding of an undetermined origin, known or suspected estrogen-dependent neoplasia. |
| Required Medical Information | Diagnosis of moderate to severe dyspareunia or atrophic vaginitis due to menopause. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan year |
| Other Criteria | None |

INTRON-A

Products Affected

- INTRON A

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Uncontrolled depression. Solid organ transplant other than liver. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon and ribavirin. |
| Required Medical Information | Diagnosis of hairy cell leukemia OR Diagnosis of Condylomata acuminata OR Diagnosis of AIDS-related Kaposi's sarcoma OR Clinically aggressive follicular lymphoma and the medication will be used concurrently with anthracycline-containing chemotherapy or is not a candidate for anthracycline-containing chemotherapy OR Malignant melanoma and the request for coverage is within 56 days of surgery and the patient is at high risk of disease recurrence OR Diagnosis of 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 Diagnosis of 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 | 1 year of age or older for HBV. 3 years of age or older for HCV. 18 years of age or older for other indications. |
| Prescriber Restrictions | None |
| Coverage Duration | Condylomata: 3 mos. HBV e antigen pos: 16 wks, e antigen neg: 48 wks. KS: 16 wks. Others: 12 mos |
| Other Criteria | None |

IRESSA

Products Affected

- IRESSA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC AND Patient has known active 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 |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |

ISTODAX

Products Affected

- ISTODAX (OVERFILL)

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of cutaneous OR peripheral T-cell lymphoma AND prior use of one systemic therapy such one of the following: a retinoid (i.e., Bexarotene (Targretin)), all-trans retinoic acid (Vesanoid), acitretin (Soriatane). |
| Age Restrictions | None |
| Prescriber Restrictions | none |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ITRACONAZOLE

Products Affected

- *itraconazole oral capsule*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of onychomycosis requires a positive laboratory test such as (potassium hydroxide-KOH preparation, fungal culture, or nail biopsy) to confirm the diagnosis. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | None |

JAKAFI

Products Affected

- JAKAFI

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of myelofibrosis (primary, post-polycythemia vera, or post-essential thrombocythemia) AND patient has two or more of the following: age older than 65 years, white blood cell count greater than $25 \times 10^9/L$, hemoglobin less than 10 g/dL, peripheral blasts more than 1%, constitutional symptoms (e.g., night sweats, fevers, unintentional weight loss, debilitating fatigue) OR diagnosis of Polycythemia Vera in patients with inadequate response to or are intolerant of hydroxyurea. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | None |

JUXTAPID

Products Affected

- JUXTAPID

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests. Pregnancy. Concomitant use with strong or moderate CYP3A4 inhibitors. |
| Required Medical Information | Diagnosis of homozygous familial hypercholesterolemia as evidenced by one of the following: A genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or autosomal recessive hypercholesterolemia (ARH) adaptor protein gene locus OR history of an untreated LDL-C concentration greater than 500 mg/dL together with either xanthoma before 10 years of age OR evidence of HeFH in both parents AND Patient has tried and had an inadequate response to the maximum tolerated dose of a high potency statin (e.g., atorvastatin), unless all statins are contraindicated |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Initial - 6 months. Renewal - 12 months |
| Other Criteria | For renewal, patient has responded to therapy with a decrease in LDL levels from baseline AND patient does not have contraindications to therapy. |

KADCYLA

Products Affected

- KADCYLA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Patient has a diagnosis of HER2-positive metastatic breast cancer and the member has been previously treated with trastuzumab and a taxane |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Prescriber has assessed the patient's hepatic function and left ventricular ejection fraction prior to initiation of therapy. Female patients of child-bearing potential had pregnancy status verified prior to the initiation of Kadcyla and have been advised of the risk of fetal harm and the need for contraception. |

KALYDECO

Products Affected

- KALYDECO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Cystic Fibrosis (Initial): Diagnosis of cystic fibrosis AND the patient has 1 mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Kalydeco potentiation based on clinical and/or in vitro assay data. (Reauthorization): Documentation of one of the following while on Kalydeco therapy: Improved lung function or stable lung function. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

KEYTRUDA

Products Affected

- KEYTRUDA INTRAVENOUS SOLUTION

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of unresectable or metastatic melanoma OR first-line treatment of metastatic non-small cell lung cancer (NSCLC) in patients with high PD-L1 expressing tumors and with no EGFR or ALK genomic tumor aberrations OR treatment of metastatic NSCLC in patients with PD-L1 expression who have disease progression on or after platinum-containing chemotherapy (patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving Keytruda) OR recurrent or metastatic squamous cell carcinoma of the head and neck in patients with disease progression on or after platinum-containing chemotherapy OR treatment of adult or pediatric patients with classical Hodgkin lymphoma (in patients who are refractory or who have relapsed after 3 or more prior lines of therapy) OR first-line treatment (in combination with pemetrexed plus carboplatin) of metastatic nonsquamous NSCLC OR locally advanced or metastatic urothelial carcinoma (in patients who are not eligible for cisplatin-containing chemotherapy, or who have had disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy) OR unresectable or metastatic solid tumors that have been identified as having a biomarker referred to as microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) OR treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 as determined by an FDA-approved test with disease progression on or after two or more prior lines of therapy including fluoropyrimidine-and platinum-containing chemotherapy and if appropriate HER2 neu-targeted therapy. |
| Age Restrictions | None |
| Prescriber Restrictions | None |

| PA Criteria | Criteria Details |
|--------------------------|-------------------------|
| Coverage Duration | Plan Year |
| Other Criteria | None |

KISQALI

Products Affected

- KISQALI 200 DOSE
- KISQALI 400 DOSE
- KISQALI 600 DOSE
- KISQALI FEMARA 200 DOSE
- KISQALI FEMARA 400 DOSE
- KISQALI FEMARA 600 DOSE

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of hormone receptor (HR)-positive, HER2-negative advanced or metastatic breast cancer and intended to be used in combination with an aromatase inhibitor in postmenopausal women |
| Age Restrictions | Age 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist. |
| Coverage Duration | Plan year |
| Other Criteria | None |

KORLYM

Products Affected

- KORLYM

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Not covered for pregnant women. Contraindicated in patients taking simvastatin, lovastatin, and CYP3A substrates with narrow therapeutic ranges, such as cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, and tacrolimus, and patients who require concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses. Women with a history of unexplained vaginal bleeding. Women with endometrial hyperplasia with atypia or endometrial carcinoma. |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

KUVAN

Products Affected

- KUVAN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Kuvan is indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4-) responsive Phenylketonuria (PKU). There are currently no pharmacogenomic tests to identify patients most likely to respond to Kuvan. No consensus exists regarding the optimal levels of blood Phe. However, based on data regarding the relationship between Phe level and brain function, the National Institutes of Health (NIH) consensus panel recommends that Phe levels be maintained between 2-6 mg/dL (120-360 micromol/L) if less than 12 years of age, 2-10 mg/dL (120-600 micromol/L) if greater than 12 and less than 18 years of age, and 2-15 mg/dL (120-900 micromol/L) if greater than 18 years of age. Initial extension will ONLY be granted for members who meet the following criteria: documented as still under the appropriate care and re-evaluations of a specialist knowledgeable in the management of PKU. Extended Approval: 6 month intervals, based on documentation of the following: still under the appropriate care and re-evaluations of a specialist knowledgeable in the management of PKU. |
| Age Restrictions | 1 month of age or older |
| Prescriber Restrictions | specialist knowledgeable in the management of PKU |
| Coverage Duration | Initial Approval: 2 months. Extended Approval: 6 month intervals |
| Other Criteria | None |

KYNAMRO

Products Affected

- KYNAMRO SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests. |
| Required Medical Information | Diagnosis of homozygous familial hypercholesterolemia as evidenced by one of the following: A) genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or autosomal recessive hypercholesterolemia (ARH) adaptor protein gene locus OR B) untreated/pre-treatment LDL greater than 500 mg/dL with at least one of the following: cutaneous or tendonous xanthoma before age 10 years, history of early vascular disease (men younger than 55 years, women younger than 60 years) on both sides of the family if parenteral LDL levels are unknown, elevated LDL cholesterol levels before lipid-lowering therapy consistent with heterozygous FH in both parents AND Patient has tried and had an inadequate response to the maximum tolerated dose of a high potency statin (e.g., atorvastatin), unless all statins are contraindicated. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Initial - 6 months. Renewal - 12 months |
| Other Criteria | For renewal, patient has responded to therapy with a decrease in LDL levels from baseline AND patient does not have contraindications to therapy. |

LARTRUVO

Products Affected

- LARTRUVO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of soft tissue sarcoma (STS), histologic subtype for which an anthracycline-containing regimen is appropriate, previous treatment failure with radiotherapy or surgery and must document being used in combination with doxorubicin for the first 8 cycles. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

LENVIMA

Products Affected

- LENVIMA 10 MG DAILY DOSE
- LENVIMA 14 MG DAILY DOSE
- LENVIMA 18 MG DAILY DOSE
- LENVIMA 20 MG DAILY DOSE
- LENVIMA 24 MG DAILY DOSE
- LENVIMA 8 MG DAILY DOSE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer OR in combination with everolimus, the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

LETAIRIS

Products Affected

- LETAIRIS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension that 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.) AND Patient has WHO Group I PAH AND pregnancy must be excluded prior to the start of therapy. Female patients of childbearing age will be educated about the potential hazards associated with Letairis use in pregnancy. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | IUD or two appropriate contraceptive methods will be used for women of childbearing potential. |

LIDOCAINE PATCH

Products Affected

- *lidocaine external patch 5 %*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | For the FDA-labeled indication of post-herpetic neuralgia, no additional criteria are required to be met. For diabetic neuropathy: the patient must have previous use and inadequate response or intolerance to Cymbalta or Lyrica. |

LONSURF

Products Affected

- LONSURF

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of 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 |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | For initial treatment: Absolute neutrophil count 1,500/mm(3) or greater or febrile neutropenia resolved, platelet count 75,000/mm(3) or greater, and grade 3 or 4 nonhematological reactions resolved to grade 0 or 1 |

LUMIZYME

Products Affected

- LUMIZYME

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of late (non-infantile) onset Pompe disease (GAA) deficiency |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

LUPRON

Products Affected

- *leuprolide acetate injection*
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- LUPRON DEPOT-PED (1-MONTH) INTRAMUSCULAR KIT 11.25 MG, 15 MG
- LUPRON DEPOT-PED (3-MONTH) INTRAMUSCULAR KIT 30 MG (PED)

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy in patients with child-bearing potential. Breastfeeding. Undiagnosed abnormal vaginal bleeding. |
| Required Medical Information | Diagnosis of one of the following: A) advanced or metastatic prostate cancer (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), B) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only) and for initial, patient has had an inadequate pain control response or patient has an intolerance or contraindication to one of the following: Danazol OR Combination [estrogen/progesterone] Oral Contraceptives OR Progestins and for retreatment course, Patient is experiencing recurrence of symptoms after an initial course of therapy with leuprolide acetate and Norethindrone acetate 5 mg daily will be co-administered, or C) Anemia due to uterine Leiomyomata (Fibroids) (3.75 mg 1-month & 11.25 mg 3-month depots only) and Patient is preoperative. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Endometriosis- 6 months, Uterine fibroids -3 months, Prostate cancer, Precocious Puberty -12 months |
| Other Criteria | For endometriosis and uterine fibroids, patient will be using nonhormonal contraception during and for 12 weeks after therapy. |

LYNPARZA

Products Affected

- LYNPARZA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Appropriate diagnosis and testing for BRCA mutation (deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA approved test) advanced ovarian cancer that has been treated with 3 or more prior lines of chemotherapy) |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

MAKENA

Products Affected

- MAKENA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Breast, cervical, hepatocellular, uterine, or vaginal cancers, hepatic or thromboembolic disease, jaundice, or vaginal bleeding |
| Required Medical Information | Supporting statement of diagnosis from physician |
| Age Restrictions | 16 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 21 weeks |
| Other Criteria | None |

MATULANE

Products Affected

- MATULANE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

MEKINIST

Products Affected

- MEKINIST

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | A documented BRAF V600E or V600K mutations as detected by an FDA-approved test |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | Mekinist is not indicated for the treatment of patients who have received prior BRAF-inhibitor therapy (i.e. Zelboraf, Tafinlar). |

MOZOBIL

Products Affected

- MOZOBIL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Patient is to undergo autologous stem cell transplantation for the treatment of non-Hodgkin's lymphoma or multiple myeloma AND Patient will concomitantly receive a daily dose of a granulocyte colony-stimulating factor (G-CSF) for 4 days prior to the first evening dose of Mozobil and on each day prior to apheresis while using Mozobil. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 4 days |
| Other Criteria | None |

MS INTERFERONS

Products Affected

- BETASERON SUBCUTANEOUS KIT
- GILENYA ORAL CAPSULE 0.5 MG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of relapsing form of multiple sclerosis OR diagnosis of first clinical episode and MRI features consistent with multiple sclerosis. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | For renewal, patient has experienced an objective response to therapy (i.e. no or slowed progression of disease) |

MYLOTARG

Products Affected

- MYLOTARG INTRAVENOUS SOLUTION RECONSTITUTED 4.5 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | INITIAL: A. Newly-diagnosed, CD33 positive acute myeloid leukemia (AML) or B. Relapsed or refractory CD33 positive AML. CONTINUATION OF THERAPY: 1) patient continues to meet initial criteria and 2) patients with newly diagnosed AML have not exceeded a maximum of 8 cycles |
| Age Restrictions | Relapsed or refractory AML: 2 years and older, Newly diagnosed AML: 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

NAGLAZYME

Products Affected

- NAGLAZYME

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis confirmed by DNA testing or an enzymatic assay showing a deficiency in N-acetylgalactosamine activity. Patient must have at least one MPS VI symptom. For re-authorization of Naglazyme, patient must demonstrate improvement in walking and/or stair-climbing capacity. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Initial approval: 6 months Extended approval: Annual review will be based on response to therapy |
| Other Criteria | If this medication is administered by a physician incident to a physicians visit, this would be covered by Medicare Part B |

NERLYNX

Products Affected

- NERLYNX

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of early stage HER2- overexpressed breast cancer. Must be used after trastuzumab therapy. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

NEUPOGEN

Products Affected

- NEUPOGEN INJECTION SOLUTION 300 MCG/ML, 480 MCG/1.6ML
- NEUPOGEN INJECTION SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | <p>Diagnosis of one of the following: A) congenital, cyclic, or idiopathic neutropenia, B) severe febrile neutropenia (FN) with the following: Has not received prophylactic pegfilgrastim and Used as adjunct to appropriate antibiotics in high-risk patients and any one of the following: 65 years or older, Uncontrolled primary disease, Pneumonia, Hypotension and multiorgan dysfunction (sepsis syndrome), Invasive fungal infection, Hospitalization when developed fever, Prior FN, Severe (ANC less than 100/mcL) or anticipated prolonged (more than 10 days) neutropenia, C) Autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, D) Undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, E) Acute myeloid leukemia and will be given after completion of induction or consolidation chemotherapy, F) Acute lymphoblastic leukemia and will be given after completion of the first few days of chemotherapy of the initial induction or first post-remission course, G) Myelodysplastic syndrome with severe neutropenia and recurrent infection, H) Receiving radiation therapy, not on chemotherapy, and expected to have prolonged delays in treatment due to neutropenia, I) Neutropenia associated with HIV infection and antiretroviral therapy, J) Aplastic anemia, K) Primary prophylaxis of FN in one of the following patients: 20% or higher risk of FN based on chemotherapy regimen OR Less than 20% risk of FN based on chemotherapy regimen with one of the following: 65 years or older, Poor performance status, Poor nutritional status, Previous FN, Extensive prior treatment including large radiation ports, Cytopenias due to bone marrow involvement by tumor, Administration of combined chemoradiotherapy, Presence of open wounds or active infections, Other serious comorbidities (including renal or liver dysfunction) or Receiving dose-dense chemotherapy regimen in breast or small cell lung cancer or non-Hodgkins lymphoma.</p> |
| Age Restrictions | None |

| PA Criteria | Criteria Details |
|--------------------------------|-------------------------|
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

NEXAVAR

Products Affected

- NEXAVAR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Squamous cell lung cancer being treated with carboplatin and paclitaxel. |
| Required Medical Information | Diagnosis of unresectable hepatocellular carcinoma OR Diagnosis of advanced renal cell carcinoma OR Diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

NICOTINE

Products Affected

- NICOTROL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Beneficiary continues to smoke |
| Required Medical Information | Beneficiary must have successful cessation at 12 weeks for one additional authorization period of 12 weeks. |
| Age Restrictions | 18 years old |
| Prescriber Restrictions | None |
| Coverage Duration | Initial: 12 weeks. Renewal: 12 weeks |
| Other Criteria | None |

NINLARO

Products Affected

- NINLARO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with Revlimid (lenalidomide) and dexamethasone. Patient has received at least one prior therapy for multiple myeloma [e.g., Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)]. |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with a hematologist/oncologist. |
| Coverage Duration | 12 months |
| Other Criteria | None |

NORTHERA

Products Affected

- NORTHERA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Request will be approved for the following indication(s): orthostatic dizziness, light-headedness, or the feeling that you are about to black out in adults with neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (i.e., Parkinson disease, multiple system atrophy, pure autonomic failure, dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy). |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

NOXAFIL

Products Affected

- NOXAFIL ORAL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concomitant treatment with sirolimus, CYP 3A4 substrates that prolong QT interval (pimozide, quinidine), HMG-CoA Reductase inhibitors primarily metabolized through CYP 3A4, or ergot alkaloids |
| Required Medical Information | Diagnosis of oropharyngeal candidiasis and patient tried itraconazole and/or fluconazole OR Medication will be used as prophylaxis of invasive Aspergillus and Candida infections and the patient is at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy. |
| Age Restrictions | 13 years of age or older for prophylaxis of invasive Aspergillus or candidal infection |
| Prescriber Restrictions | None |
| Coverage Duration | 12 weeks |
| Other Criteria | None |

NUEDEXTA

Products Affected

- NUEDEXTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Patient diagnosis of pseudobulbar affect. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

NUPLAZID

Products Affected

- NUPLAZID ORAL TABLET 17 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Parkinson disease psychosis including hallucinations and/or delusions |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ODOMZO

Products Affected

- ODOMZO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma AND one of the following: 1) Cancer has recurred following surgery or radiation therapy or 2) Patient is not a candidate for surgery or radiation therapy |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or dermatologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

OPDIVO

Products Affected

- OPDIVO INTRAVENOUS SOLUTION
100 MG/10ML, 40 MG/4ML

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of BRAF V600 wild-type or BRAF V600 mutation-positive unresectable or metastatic melanoma and used as single agent OR unresectable or metastatic melanoma in combination with ipilimumab OR adjuvant treatment of melanoma in patients with lymph node involvement or metastatic disease who have undergone complete resection OR treatment of patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy and patients with EGFR or ALK genomic tumor aberrations should have disease progression (on FDA-approved EGFR- or ALK-directed therapy) prior to receiving nivolumab OR advanced renal cell carcinoma in combination with ipilimumab OR as monotherapy in patients who have received prior anti-angiogenic therapy OR recurrent or metastatic squamous cell carcinoma of the head and neck in patients with disease progression on or after platinum-based chemotherapy OR classical Hodgkin lymphoma in patients who have relapsed or progressed after autologous hematopoietic stem cell transplant (HSCT) and brentuximab vedotin OR classical Hodgkin lymphoma that has relapsed or progressed after 3 or more lines of systemic therapy that includes an autologous hematopoietic stem cell transplantation (HSCT) OR locally advanced or metastatic urothelial carcinoma in patients with disease progression on or following platinum-containing therapy or within 12 months of neoadjuvant or adjuvant treatment with a platinum-containing therapy OR microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer with progression after treatment of fluoropyrimidine, oxaliplatin, and irinotecan OR treatment of hepatocellular cancer, after disease progression on or intolerance to sorafenib therapy. |
| Age Restrictions | 12 years of age or older |
| Prescriber Restrictions | None |

| PA Criteria | Criteria Details |
|--------------------------|-------------------------|
| Coverage Duration | Plan Year |
| Other Criteria | None |

OPIOID ANTAGONIST

Products Affected

- *buprenorphine hcl sublingual*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

OPSUMIT

Products Affected

- OPSUMIT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension WHO group I AND diagnosis was confirmed by right heart catheterization AND female patients are enrolled in the OPSUMIT REMS program. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months - initial. 12 months - renewal |
| Other Criteria | IUD or two appropriate contraceptive methods will be used for women of childbearing potential. |

ORFADIN

Products Affected

- ORFADIN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ORKAMBI

Products Affected

- ORKAMBI ORAL TABLET

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Initial Therapy: Must have diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test. Continuation of therapy: Documentation patient is tolerating and responding to medication (i.e., improved FEV1, weight gain, decreased exacerbations, etc.) |
| Age Restrictions | Must be greater than or equal to 6 years of age |
| Prescriber Restrictions | Must be prescribed by, or in conjunction with, a pulmonologist or is from a CF center accredited by the Cystic Fibrosis Foundation |
| Coverage Duration | Plan Year |
| Other Criteria | None |

OSPHERA

Products Affected

- OSPHERA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | Vaginal bleeding or dysfunctional uterine bleeding of an undetermined origin, known or suspected estrogen-dependent neoplasia, acute thromboembolism or a past history of thromboembolic disease (including patients with a history of DVT, pulmonary embolism, retinal vein thrombosis, stroke, or myocardial infarction, known or suspected pregnancy. |
| Required Medical Information | Diagnosis of moderate to severe dyspareunia or atrophic vaginitis due to menopause. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan year |
| Other Criteria | None |

OXANDROLONE

Products Affected

- *oxandrolone oral*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Breast or prostate cancer in men. Breast cancer in women with hypercalcemia. Pregnancy. Nephrosis or nephrotic phase of nephritis. Hypercalcemia. |
| Required Medical Information | Patient is receiving treatment as an adjunct therapy to promote weight gain and has one of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons and Patient has had an inadequate response, intolerance, or contraindication to nutritional supplements and a nutritional consult was performed OR Oxandrin (oxandrolone) will be used to counterbalance protein catabolism associated with chronic corticosteroid administration OR Patient has bone pain associated with osteoporosis. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Osteoporosis bone pain: 1 month. Other diagnoses: 3 months |
| Other Criteria | For renewal, patient has experienced an objective improvement (i.e. weight gain, increase in lean body mass, or reduction in muscle pain/weakness) |

PANRETIN

Products Affected

- PANRETIN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist or HIV specialist |
| Coverage Duration | Plan Year |
| Other Criteria | Approve for continuation of prior therapy |

PCSK9 INHIBITOR

Products Affected

- PRALUENT SUBCUTANEOUS SOLUTION PEN-INJECTOR
- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | <p>FOR PRALUENT: MUST MEET CRITERIA #1 OR #3. FOR REPATHA: MUST MEET CRITERIA #1, #2 OR #3. 1. Diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by genotyping OR Simon Broome criteria: Total cholesterol greater than 290mg/dL or LDL cholesterol greater than 190mg/dL, PLUS ONE OF THE FOLLOWING: Tendon xanthomas in patient, or 1st degree relative (parent, sibling, child), or 2nd degree relative (grandparent, uncle, aunt) OR DNA-based evidence of LDL receptor mutation, familial defective apo B-100, or PCSK9 mutation 2a. Myocardial infarction prophylaxis, stroke prophylaxis, and to reduce risk of coronary revascularization in patients with established CVD OR 2b. Diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by genotyping OR diagnosis based on the following: a. History of untreated LDL-C greater than 500 mg/dL AND xanthoma before 10 years of age OR b. Documentation of HeFH in both parents 3. Diagnosis of clinical atherosclerotic cardiovascular disease (CVD) as defined as one of the following: a. acute coronary syndrome, b. history of myocardial infarction, c. stable/unstable angina, d. coronary or other arterial revascularization, e. stroke, f. transient ischemic stroke (TIA), g. peripheral arterial disease presumed to be atherosclerotic region. AND MEETS CRITERIA #4, #5, and #6, 4. Provide baseline and current LDL-C 5. LDL-C greater than or equal to 70 mg/dL 6. Used in combination with maximally tolerated high-intensity statin OR MEETS CRITERIA #7 AND #8. 7. Statin intolerant 8. LDL-C greater than or equal to 70 mg/dL</p> <p>CONTINUING THERAPY: 1. Documented response to Praluent or Repatha, defined as ONE of the following: a. The patient is tolerating medication b. Will continue to be used in combination with maximally tolerated statin (unless statin intolerant).</p> |
| Age Restrictions | Repatha: 13 years of age or older for diagnosis HoFM, Diagnosis CVD or HeFH AND Praluent or Repatha : 18 years of age or older |

| PA Criteria | Criteria Details |
|--------------------------------|--|
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or lipid specialist |
| Coverage Duration | Initial approval: 8 weeks, Renewal approval: Plan Year |
| Other Criteria | None |

PEGASYS

Products Affected

- PEGASYS PROCLICK
- PEGASYS SUBCUTANEOUS SOLUTION

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Uncontrolled depression. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon. |
| Required Medical Information | Chronic hepatitis B: Diagnosis of chronic hepatitis B infection and patient is without decompensated liver disease. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance |
| Age Restrictions | HCV: 18 years of age or older if used as triple therapy, otherwise 5 years of age or older. Hepatitis B: 3 years of age or older. |
| Prescriber Restrictions | ID specialist, Gastroenterologist, Oncologist |
| Coverage Duration | HBV - 12 months. HCV: Initial - 12 weeks. Renewal - duration based on medically accepted labeling. |
| Other Criteria | None |

POMALYST

Products Affected

- POMALYST

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Documentation of ALL of the following: 1. Disease has progressed within 60 days of completion of the last therapy 2. If female of reproductive potential ALL of the below: Two negative pregnancy tests obtained prior to initiating therapy with Pomalyst, monthly negative pregnancy tests during therapy 3. Patient has been counseled about the use of reliable contraception before, during, and 1 month after initiation of therapy with Pomalyst 4. Patient assessment to determine if prophylactic aspirin or antithrombic treatment (warfarin, clopidogrel) will need to be taken to reduce the risk of VTE (embolism, stroke) 5. Registered and certified to be compliant with Pomalyst REMS (Risk Evaluation and Mitigation Strategy) program |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist or hematologist |
| Coverage Duration | Plan Year |
| Other Criteria | A documented diagnosis of multiple myeloma and received at least two prior therapies including lenalidomide (Revlimid) and bortezomib (Velcade) |

PROLEUKIN

Products Affected

- PROLEUKIN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Metastatic Renal Cell Carcinoma or Metastatic Melanoma: Good neurologic or ambulatory performance status (i.e., 0 or 1 by Eastern Cooperative Oncology Group, 70-100% by Karnofsky scoring system). Adequate organ function (i.e., heart, lungs, kidneys) as determined by all of the following: normal cardiac stress test results, Forced expiratory volume in 1 second (FEV1) greater than 2 L on pulmonary function tests, creatinine concentration 1.5 mg/dL or less. |
| Age Restrictions | Metastatic Renal Cell Carcinoma or Metastatic Melanoma: 18 years and older |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Metastatic Renal Cell Carcinoma or Metastatic Melanoma: 3 months |
| Other Criteria | None |

PROMACTA

Products Affected

- PROMACTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Documented diagnosis of chronic, relapsed or refractory idiopathic thrombocytopenic purpura or Chronic hepatitis C infection associated thrombocytopenia OR severe aplastic anemia with insufficient response to immunosuppressive therapy. |
| Age Restrictions | Patients 1 year of age or older. |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Requests for coverage for thrombocytopenia in chronic hepatitis C patients will be approved if the platelet count is less than 50 billion cells/L. Promacta should be withheld when platelet counts exceed 400,000/mcL or if there's no response within 4 weeks of treatment at the maximum dose (75mg/day). Not covered in the presence of clinical symptoms of liver injury or evidence of hepatic decompensation. |

PROVIGIL

Products Affected

- *modafinil*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA)/hypopnea syndrome OR Diagnosis of excessive sleepiness associated with narcolepsy and patient has tried, is unable to tolerate, or has contraindication(s) to at least one other central nervous system stimulant (e.g., methylphenidate, mixed amphetamine salts, dextroamphetamine) OR Diagnosis of excessive sleepiness associated with shift work disorder |
| Age Restrictions | 17 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

QUININE SULFATE

Products Affected

- *quinine sulfate oral*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Prolongation of QT interval. Glucose-6-phosphate dehydrogenase deficiency. Myasthenia gravis. Known hypersensitivity to mefloquine or quinidine. Optic neuritis. |
| Required Medical Information | Patient has a diagnosis of one of the following: A) uncomplicated Plasmodium falciparum malaria B) uncomplicated Plasmodium vivax malaria C) babesiosis |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | One month |
| Other Criteria | None |

RADICAVA

Products Affected

- RADICAVA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | Sulfite hypersensitivity |
| Required Medical Information | Diagnosis of amyotrophic lateral sclerosis and must meet all of the following: functionality retained most activities of daily living (defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale, normal respiratory function defined as percent-predicted forced vital capacity values of percent FVC greater or equal to 80 percent, disease duration of 2 years or less). |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 6 months |
| Other Criteria | None |

REGRANEX

Products Affected

- REGRANEX

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diabetic Neuropathic Ulcers: Diabetic patient with ulcer wound. Treatment will be given in combination with ulcer wound care (e.g., debridement, infection control, and/or pressure relief). |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Diabetic Neuropathic Ulcers: Maximum 5 months. |
| Other Criteria | None |

REVATIO

Products Affected

- *sildenafil citrate oral tablet 20 mg*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Nitrate therapy |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension that 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.) AND Patient has WHO Group I PAH |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

REVLIMID

Products Affected

- REVLIMID

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of multiple myeloma and patient has received at least one prior therapy and medication will be used in combination with dexamethasone OR diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities OR diagnosis of mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib AND patient is enrolled in the Revlimid REMS Program |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Male and female patients of child-bearing potential should be instructed on the importance of proper utilization of appropriate contraceptive methods for Revlimid use. Patients should be monitored for signs and symptoms of thromboembolism. |

RITUXAN

Products Affected

- RITUXAN INTRAVENOUS SOLUTION

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of non-Hodgkin's lymphoma OR Diagnosis of chronic lymphocytic leukemia OR Diagnosis of granulomatosis with polyangiitis and is receiving concurrent glucocorticoid therapy OR Diagnosis of microscopic polyangiitis and is receiving concurrent glucocorticoid therapy OR Diagnosis of moderate to severe rheumatoid arthritis, in combination with methotrexate, and patient had an inadequate response, intolerance, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs for at least 3 consecutive months and patient has tried and had an inadequate response, intolerance, or contraindication to either Humira or Enbrel. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Monitored for pulmonary toxicity |

RUBRACA

Products Affected

- RUBRACA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of 1. deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer and all of the following criteria (A-E): A. BRCA mutation positive as detected by an approved FDA laboratory test, B. Previous trial/failure with two or more chemotherapy regimens, C. Used as monotherapy, D. Agreement of provider to perform a complete blood count (CBC) at baseline and monthly thereafter, E. Women of reproductive potential must use an effective method of contraception during therapy and for 6 months after the last dose. OR 2. recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and all of the following (A-D): A. Complete or partial response to platinum-based chemotherapy B. Used as monotherapy C. Agreement of provider to perform a complete blood count (CBC) at baseline and monthly thereafter, D. Women of reproductive potential must use an effective method of contraception during therapy and for 6 months after the last dose. |
| Age Restrictions | Age 18 years and older |
| Prescriber Restrictions | Hematologist or Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

RYDAPT

Products Affected

- RYDAPT

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | Angioedema |
| Required Medical Information | Diagnosis of treatment naive FLT3 mutation-positive acute myelogenous leukemia (AML) AND Must be used in combination with standard cytarabine and daunorubicin induction and consolidation therapy OR Diagnosis of systemic mastocytosis |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a oncologist |
| Coverage Duration | Plan year |
| Other Criteria | None |

SAMSCA

Products Affected

- SAMSCA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Documented concurrent use of strong CYP3A inhibitors (for example: ketoconazole, clarithromycin, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, telithromycin) |
| Required Medical Information | Treatment with Samsca is being initiated or re-initiated in a hospital where serum sodium can be monitored closely |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 30 days |
| Other Criteria | None |

SIGNIFOR

Products Affected

- SIGNIFOR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Cushing's disease (initial): Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Either pituitary surgery has not been curative for the patient OR patient is not a candidate for pituitary surgery. (Reauthorization): Documentation of positive clinical response to Signifor therapy. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Initial: 6 months trial. Reauthorization: 12 months if demonstrated benefit |
| Other Criteria | None |

SIVEXTRO

Products Affected

- SIVEXTRO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Patient does NOT have any FDA labeled contraindication(s) to the requested agent |
| Required Medical Information | <p>1. If requested agent is prescribed by an infectious disease specialist or the prescriber has consulted with an infectious disease specialist on treatment of this patient AND BOTH of the following: a. ONE of the following: i. Patient has a documented acute bacterial skin and skin structure infection (ABSSSI) defined as a bacterial infection of the skin with a lesion size area of at least 75 cm² (lesion size measured by the area of redness, edema, or induration) OR ii. Use of requested agent is for an indication that is supported by compendia or the prescriber has submitted additional documentation supporting the requested therapeutic use AND b. Dose is within the FDA labeled dosage OR 2. If the requested agent is NOT prescribed by an infectious disease specialist or the prescriber has NOT consulted with an infectious disease specialist on treatment of this patient AND ALL of the following: a. Patient has a documented acute bacterial skin and skin structure infection (ABSSSI) defined as a bacterial infection of the skin with a lesion size area of at least 75 cm² (lesion size measured by the area of redness, edema, or induration) AND b. ONE of the following: i. Infection is due to Staphylococci that are resistant to beta lactams, macrolides, clindamycin, tetracycline, and co-trimoxazole, or vancomycin (e.g. MRSA) or patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to beta lactams, macrolides, clindamycin, tetracyclines, and cotrimoxazole, or vancomycin OR ii. Infection is due to vancomycin-resistant Enterococcus faecalis or patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to vancomycin AND c. Dose is within the FDA labeled dosage</p> |
| Age Restrictions | None |
| Prescriber Restrictions | None |

| PA Criteria | Criteria Details |
|--------------------------|--|
| Coverage Duration | Approval will be 6 days for FDA labeled indications or 30 days for all other indications |
| Other Criteria | None |

SOLTAMOX

Products Affected

- SOLTAMOX

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis for use. Documentation of inability to swallow tablet formulation. |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

SOMATULINE

Products Affected

- SOMATULINE DEPOT SUBCUTANEOUS SOLUTION 120 MG/0.5ML, 60 MG/0.2ML, 90 MG/0.3ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis for use: Acromegaly in patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option., OR have failed an adequate trial of octreotide. DOSING :(initial) 90 mg deep SUBQ injection every 4 weeks for 3 months (maintenance) after 3 months, for GH levels greater than 1 ng/mL but less than or equal to 2.5ng/mL, normal insulin-like growth factor-1 (IGF-1), and controlled symptoms, continue 90 mg every 4 weeks:for GH greater than 2.5ng/mL, elevated IGF-1, and/or uncontrolled symptoms, increase to 120 mg every 4 weeks: for GH of 1 ng/mL or less, normal IGF-1, and controlled symptoms, reduce dose to 60 mg every 4 weeks: thereafter, adjust dose according to response. |
| Age Restrictions | Adults: 18 years and older. |
| Prescriber Restrictions | None |
| Coverage Duration | Initial approval: 3 months. Extended approval: 3 months with dose adjusted according to response |
| Other Criteria | If this medication is administered by a physician incident to a physicians visit, this would be covered by Medicare Part B |

SOMAVERT

Products Affected

- SOMAVERT SUBCUTANEOUS SOLUTION RECONSTITUTED 10 MG, 15 MG, 20 MG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | IV administration of Somavert, concomitant use of Sandostatin or Somatuline. |
| Required Medical Information | Diagnosis of acromegaly was confirmed by an elevated IGF-1 level or elevated GH level with a glucose tolerance test. Patient has tried and failed at least a 3 month trial of Sandostatin or Somatuline. For renewal, reduction in IGF-1 level from baseline. |
| Age Restrictions | None |
| Prescriber Restrictions | Endocrinologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

SPRYCEL

Products Affected

- SPRYCEL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | Coverage is provided for the following indications. 1. Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. 2. Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. 3. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy. |

STIVARGA

Products Affected

- STIVARGA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | A documented diagnosis of metastatic colorectal cancer AND documentation of prior therapy with ALL of the following per the indication: 1. (fluoropyrimidine-, oxaliplatin-, and irinotecan)-based chemotherapy 2. bevacizumab (Avastin) 3. panitumumab (Vectibix) OR cetuximab (Erbix) (for KRAS mutation-negative patients only) OR a documented diagnosis of locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate (Gleevec) and sunitinib malate (Sutent) OR a documented diagnosis of hepatocellular carcinoma in patients previously treated with sorafenib (Nexavar). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

SUTENT

Products Affected

- SUTENT

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma OR adjuvant treatment in renal cell carcinoma for patients at high risk of recurrence following nephrectomy. Gastrointestinal stromal tumor (GIST): Diagnosis of GIST after disease progression on or intolerance to Gleevec (imatinib). Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |

SYLATRON

Products Affected

- SYLATRON SUBCUTANEOUS KIT
200 MCG, 300 MCG, 600 MCG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

SYMDEKO

Products Affected

- SYMDEKO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of cystic fibrosis and patient is homozygous for the F508del mutation OR has mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor verified by an FDA-approved CF mutation test. |
| Age Restrictions | 12 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

SYNAGIS

Products Affected

- SYNAGIS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Patient will use palivizumab for immunoprophylaxis of respiratory syncytial virus (RSV) during the peak months of infection in the patient's geographic region AND Patient meets one of the following criteria: A) Infants born at 28 weeks, six days gestation or earlier and who are younger than 12 months of age at the start of the RSV season OR B) Infants born at 29 to 31 weeks, six days gestation and who are younger than six months of age at the start of the RSV season OR C) Infants born at 32 to 34 weeks, six days gestation and who are younger than three months of age at the start of RSV season with at least one of the following risk factors may be dosed until 90 days of age: Child care attendance or Sibling younger than five years of age living in the same household (who is not a multiple birth younger than one year of age) OR D) Infants and children younger than one year of age at the start of RSV season with either congenital abnormalities of the airway or neuromuscular disease that compromises handling of respiratory secretions OR E) Infants and children younger than two years of age with hemodynamically significant congenital heart disease and who have at least one of the following criteria: Receiving medication to control congestive heart failure, Has moderate to severe pulmonary hypertension, or Has cyanotic heart disease OR F) Infants and children younger than two years of age who have received medical therapy (oxygen, bronchodilator, diuretic, or corticosteroid therapy) for chronic lung disease within six months of the start of the RSV season |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Approve 5 doses based on patient body weight |

SYNAREL

Products Affected

- SYNAREL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | SYNAREL should not be administered to patients who are hypersensitive to GnRH, GnRH agonist analogues, or any of the excipients of SYNAREL, have undiagnosed vaginal bleeding, are pregnant or may become pregnant as major fetal abnormalities were observed in rats (not applicable when used in in vitro fertilization programs), are breast feeding. |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

SYPRINE

Products Affected

- *trientine hcl*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Wilson's disease and intolerance to penicillamine |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

TABLOID

Products Affected

- TABLOID

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist or hematologist |
| Coverage Duration | Plan Year |
| Other Criteria | Approve for continuation of prior therapy |

TAFINLAR

Products Affected

- TAFINLAR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic melanoma with BRAF V600E or V600K mutations as detected by FDA approved test used in combination with trametinib. For patients with BRAF V600E mutation ONLY confirmed by FDA approved test, Tafinlar can be used as monotherapy. |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | Tafinlar should not be used in patients with wild-type BRAF melanoma due to the potential risk of tumor promotion in these patients |

TAGRISSO

Products Affected

- TAGRISSO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic EGFR mutation-positive, non-small cell lung cancer (NSCLC) OR metastatic, non-small cell lung cancer with confirmed presence of T790M EGFR mutation AND whose disease has progressed on or after EGFR tyrosine kinase inhibitor based therapy. Diagnosis confirmed by an FDA-approved test. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

TARCEVA

Products Affected

- TARCEVA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | For the diagnosis of locally advanced, unresectable, or metastatic carcinoma of pancreas, Tarceva is used in combination with gemcitabine. For the diagnosis of locally advanced or metastatic non-small cell lung cancer, the patient has met one of the following: 1. The patient has failed one or more prior chemotherapy regimens, such as platinum based chemotherapy OR 2. The patient has an epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation which requires no prerequisite therapy. |

TARGRETIN

Products Affected

- *bexarotene*
- TARGRETIN EXTERNAL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Definite diagnosis of cutaneous T-cell lymphoma (CTCL) AND refractory to any prior systemic therapy (such as methotrexate) |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

TASIGNA

Products Affected

- TASIGNA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | Coverage is provided for the treatment of newly diagnosed patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase OR the treatment of chronic phase (CP) and accelerated phase (AP) Ph+ CML in patients resistant to or intolerant to prior therapy that included a tyrosine-kinase inhibitor. |

TAZORAC

Products Affected

- *tazarotene external*
- TAZORAC EXTERNAL GEL
- TAZORAC EXTERNAL CREAM 0.05 %

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

THALOMID

Products Affected

- THALOMID

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of multiple myeloma that is newly diagnosed and is receiving concurrent dexamethasone OR of Acute treatment of cutaneous manifestations of moderate/severe erythema nodosum leprosum AND medication will not be used as monotherapy in the presence of moderate to severe neuritis OR Maintenance treatment for prevention/suppression of cutaneous manifestations of erythema nodosum leprosum recurrence |
| Age Restrictions | 12 years of age or older |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | AS, ulcers-1 month. ENL, MM-End of year. WM, GVHD, primary brain tumor-6 months. Other uses-3 months |
| Other Criteria | Patients are monitored for signs and symptoms of thromboembolism. Male and female patients of child-bearing potential are instructed on the importance of proper utilization of appropriate contraceptive methods. |

TRACLEER

Products Affected

- TRACLEER

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Receiving concomitant cyclosporine A or glyburide therapy. Aminotransferase elevations are accompanied by signs or symptoms of liver dysfunction or injury or increases in bilirubin at least 2 times the upper limit of normal. |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension that 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.) AND Patient has WHO Group I PAH AND Patient has New York Heart Association (NYHA) Functional Class II-IV AND pregnancy must be excluded prior to the start of therapy and will be prevented thereafter with two forms of reliable contraception in female patients of reproductive potential. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months - initial. 12 months - renewal |
| Other Criteria | None |

TRELSTAR

Products Affected

- TRELSTAR MIXJECT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of FDA approved indications not otherwise excluded from Part D AND palliative treatment of advanced prostate cancer, central precocious puberty, endometrial hyperplasia, endometriosis, fibrocystic disease of breast, uterine leiomyoma |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

TYKERB

Products Affected

- TYKERB

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | Coverage is provided in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab OR in combination with letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated. |

TYMLOS

Products Affected

- TYMLOS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of postmenopausal osteoporosis AND a history of osteoporotic fracture, multiple risk factors for fracture, AND have failed or are intolerant to other available osteoporosis therapy (i.e. bisphosphonate, prolia) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan year |
| Other Criteria | None |

TYSABRI

Products Affected

- TYSABRI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | History of progressive multifocal leukoencephalopathy. |
| Required Medical Information | Diagnosis of relapsing form of multiple sclerosis and medication will be used as monotherapy and patient had an inadequate response, intolerance, or contraindication to conventional therapy with one of the following: An interferon beta product, Copaxone, Gilenya OR Diagnosis of moderate to severe active Crohn's disease and medication will not be used in combination with immunosuppressants or inhibitors of tumor necrosis factor-alfa and patient had an inadequate response, intolerance, or contraindication to any of the following: Humira, Remicade, or Cimzia. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | None |
| Coverage Duration | MS - 12 months. CD, initial - 3 months, renewal - 12 months. |
| Other Criteria | Patient and physician are registered in the TOUCH prescribing program. For renewal, patient had an objective response to therapy (e.g., decreased flare). |

UPTRAVI

Products Affected

- UPTRAVI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension (WHO Group 1) was confirmed by right heart catheterization AND Patient has tried and had an insufficient response to at least one other PAH agent (e.g., sildenafil) therapy. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

VARIZIG

Products Affected

- VARIZIG INTRAMUSCULAR SOLUTION

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Medication will be given through the intramuscular route AND the medication will be used for passive immunization of varicella. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 1 month |
| Other Criteria | None |

VELCADE

Products Affected

- VELCADE INJECTION

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Multiple Myeloma OR Mantle Cell Lymphoma (MCL). For previously untreated Multiple Myeloma patients, Velcade will be used in combination with melphalan and prednisone. For previously untreated MCL patients, Velcade will be used in combination with rituximab, cyclophosphamide, doxorubin, and prednisone. |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist or hematologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

VENCLEXTA

Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | CLL for patients with 17p deletion and have had at least 1 prior therapy |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | plan year |
| Other Criteria | None |

VERZENIO

Products Affected

- VERZENIO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | BREAST CANCER (1) Patient must have a diagnosis of advanced or metastatic breast cancer AND (2a) must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy OR (2b) 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 OR (2c) used as initial endocrine-based treatment in combination with an aromatase inhibitor AND (3) disease is hormone receptor positive AND human epidermal growth factor 2 (HER2)- negative |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

VORICONAZOLE

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | Infectious Disease Specialist |
| Coverage Duration | 6 months |
| Other Criteria | None |

VOTRIENT

Products Affected

- VOTRIENT

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

VYXEOS

Products Affected

- VYXEOS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of therapy related acute myeloid leukemia (t-AML) or acute myeloid leukemia with myelodysplasia related changes (AML-MRC). If the patient has the diagnosis of therapy related acute myeloid leukemia (t-AML), it must be newly diagnosed. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | B vs D coverage determination per CMS guidelines |

XALKORI

Products Affected

- XALKORI

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Supporting statement of diagnosis from the physician that establishes the cancer as anaplastic lymphoma kinase (ALK)-positive or ROS1-positive non-small cell lung cancer (NSCLC) |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

XGEVA

Products Affected

- XGEVA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Uncorrected hypocalcemia |
| Required Medical Information | 1.) Patient has bone metastases from a solid tumor. OR 2.) Patient has or giant cell tumor of the bone that is unresectable or where surgical resection is likely to result in severe morbidity. OR 3.) Patient has hypercalcemia of malignancy refractory to bisphosphonate therapy. OR 4.) Prevention of skeletal related events in patient with multiple myeloma. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

XIFAXAN

Products Affected

- XIFAXAN

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | 18 years of age and older (Xifaxan 550mg) |
| Prescriber Restrictions | None |
| Coverage Duration | Hepatic encephalopathy-6 months, travelers diarrhea(200mg tab)-3 days, IBS-D(550mg tab) for 14 days |
| Other Criteria | None |

XOLAIR

Products Affected

- XOLAIR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | For ASTHMA: 1) Diagnosis of moderate to severe persistent allergic asthma AND 2) Evidence of specific allergic sensitivity (confirmed by positive skin test (i.e. prick/puncture test), blood test for a specific IgE (i.e., radioallergosorbent test), or in vitro reactivity to a perennial aeroallergen) AND 3) Pretreatment serum IgE levels greater than 30 and less than 700 IU/mL AND 4) Symptoms are not adequately controlled with maximally tolerated dose of inhaled corticosteroid (ICS) plus long-acting beta2-agonist (LABA) for at least 3 months OR member is intolerant to ICS or LABA OR member has a contraindication to ICS or LABA. For URTICARIA: 1) diagnosis of chronic idiopathic urticaria AND 2) beneficiary remains symptomatic despite H1 antihistamine treatment. |
| Age Restrictions | 6 years of age and older |
| Prescriber Restrictions | Asthma specialist (i.e., allergist, immunologist, or pulmonologist) or dermatologist |
| Coverage Duration | Initial: 6 months trial. Extended approval: 6 months if demonstrated benefit |
| Other Criteria | If this medication is administered by a physician incident to a physicians visit, this would be covered by Medicare Part B |

XURIDEN

Products Affected

- XURIDEN

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Hereditary orotic aciduria. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

YERVOY

Products Affected

- YERVOY INTRAVENOUS SOLUTION
50 MG/10ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

YONDELIS

Products Affected

- YONDELIS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis and lab values: ANC, platelet count, creatine phosphokinase, and left ventricular ejection fraction. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Must be prescribed by an oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

YONSA

Products Affected

- YONSA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | A) Diagnosis of metastatic castration-resistant prostate cancer, and used in combination with methylprednisolone, B) Documented history of trial with, inadequate treatment response, adverse event, or contraindication to Zytiga. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or urologist |
| Coverage Duration | 12 months |
| Other Criteria | None |

ZAVESCA

Products Affected

- *miglustat*
- ZAVESCA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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 | Plan Year |
| Other Criteria | None |

ZEJULA

Products Affected

- ZEJULA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer AND patient had a complete or partial response to platinum-based chemotherapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a oncologist or gynecologist |
| Coverage Duration | Plan year |
| Other Criteria | None |

ZELBORAF

Products Affected

- ZELBORAF

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | Oncologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ZOLINZA

Products Affected

- ZOLINZA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | None |
| Required Medical Information | None |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |

ZYVOX

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Not covered with concomitant use of MAOI therapy |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | VRE: 4 weeks. Nosocomial and community acquired pneumonia: 3 weeks. All other indications: 2 weeks |
| Other Criteria | None |

PART B VERSUS PART D

Products Affected

- ABELCET
- ABRAXANE
- *acetylcysteine inhalation*
- *acyclovir sodium intravenous solution*
- ADRIAMYCIN INTRAVENOUS SOLUTION
- ADRUCIL INTRAVENOUS SOLUTION 500 MG/10ML
- *albuterol sulfate inhalation*
- AMBISOME
- AMINOSYN II INTRAVENOUS SOLUTION 10 %, 8.5 %
- AMINOSYN II/ELECTROLYTES
- AMINOSYN/ELECTROLYTES
- AMINOSYN-HBC
- AMINOSYN-PF
- AMINOSYN-RF
- *amphotericin b injection*
- *ampicillin-sulbactam sodium injection*
- *ampicillin-sulbactam sodium intravenous solution reconstituted 15 (10-5) gm*
- *aprepitant*
- ASTAGRAF XL
- AVASTIN INTRAVENOUS SOLUTION 400 MG/16ML
- *azacitidine*
- AZASAN
- *azathioprine oral*
- *azathioprine sodium*
- BENLYSTA INTRAVENOUS
- BICNU
- *bleomycin sulfate injection solution reconstituted 30 unit*
- *budesonide inhalation*
- *busulfan*
- *calcitonin (salmon)*
- *calcitriol intravenous solution 1 mcg/ml*
- *calcitriol oral*
- CAPASTAT SULFATE
- *carboplatin intravenous solution 150 mg/15ml*
- *caspofungin acetate*
- *chlorpromazine hcl injection solution 50 mg/2ml*
- *chlorpromazine hcl oral tablet 10 mg, 25 mg*
- *cisplatin intravenous solution 100 mg/100ml, 50 mg/50ml*
- *cladribine intravenous solution 10 mg/10ml*
- CLINIMIX E/DEXTROSE (2.75/5)
- CLINIMIX E/DEXTROSE (4.25/10)
- CLINIMIX E/DEXTROSE (4.25/25)
- CLINIMIX E/DEXTROSE (5/15)
- CLINIMIX/DEXTROSE (2.75/5)
- CLINIMIX/DEXTROSE (4.25/10)
- CLINIMIX/DEXTROSE (4.25/20)
- CLINIMIX/DEXTROSE (4.25/25)
- CLINIMIX/DEXTROSE (4.25/5)
- CLINIMIX/DEXTROSE (5/15)
- CLINIMIX/DEXTROSE (5/20)
- CLINIMIX/DEXTROSE (5/25)
- *clofarabine*
- *cromolyn sodium inhalation*
- *cyclophosphamide oral capsule*
- *cyclosporine intravenous*
- *cyclosporine modified*
- *cyclosporine oral capsule*
- CYRAMZA
- *cytarabine (pf) injection solution 100 mg/ml*
- *cytarabine injection solution*
- *dacarbazine intravenous solution reconstituted 200 mg*
- *dactinomycin*
- *daptomycin intravenous solution reconstituted 500 mg*
- *daunorubicin hcl intravenous injectable*
- *decitabine*
- DEPO-PROVERA INTRAMUSCULAR SUSPENSION 400 MG/ML
- *dexrazoxane intravenous solution reconstituted 250 mg*
- *diphtheria-tetanus toxoids dt*

- *docetaxel intravenous concentrate 80 mg/4ml*
- *docetaxel intravenous solution 160 mg/16ml, 80 mg/8ml*
- *doripenem intravenous solution reconstituted 500 mg*
- *doxorubicin hcl intravenous solution*
- *doxorubicin hcl liposomal*
- *duramorph*
- EMEND ORAL SUSPENSION RECONSTITUTED
- ENGERIX-B INJECTION
- *epirubicin hcl intravenous solution 200 mg/100ml*
- *etoposide intravenous solution 100 mg/5ml, 500 mg/25ml*
- FASLODEX INTRAMUSCULAR SOLUTION 250 MG/5ML
- *fluconazole in sodium chloride intravenous solution 200-0.9 mg/100ml-%, 400-0.9 mg/200ml-%*
- *fludarabine phosphate intravenous solution reconstituted*
- *fluorouracil intravenous solution 2.5 gm/50ml, 5 gm/100ml*
- FREAMINE HBC
- GAMASTAN S/D INTRAMUSCULAR INJECTABLE (10ML), (2ML)
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- *ganciclovir sodium intravenous solution reconstituted*
- *gemcitabine hcl intravenous solution reconstituted 1 gm*
- GENGRAF ORAL CAPSULE 100 MG, 25 MG
- GENGRAF ORAL SOLUTION
- *granisetron hcl intravenous solution 0.1 mg/ml, 1 mg/ml*
- *granisetron hcl oral*
- *heparin (porcine) in d5w*
- *heparin sod (porcine) in d5w intravenous solution 100 unit/ml*
- HEPATAMINE
- HERCEPTIN
- *idarubicin hcl intravenous solution 10 mg/10ml*
- *ifosfamide intravenous solution reconstituted 1 gm*
- IMOVAX RABIES
- *ipratropium bromide inhalation*
- *ipratropium-albuterol*
- *irinotecan hcl intravenous solution 100 mg/5ml*
- KEPIVANCE
- KYPROLIS INTRAVENOUS SOLUTION RECONSTITUTED 30 MG, 60 MG
- *leucovorin calcium injection solution reconstituted 100 mg, 350 mg*
- *levoleucovorin calcium intravenous solution*
- *levoleucovorin calcium intravenous solution reconstituted 50 mg*
- *melfhalan hcl*
- *mesna*
- *methotrexate oral*
- *methotrexate sodium (pf) injection solution 250 mg/10ml, 50 mg/2ml*
- *methotrexate sodium injection solution 250 mg/10ml*
- *methotrexate sodium injection solution reconstituted*
- *metoprolol tartrate intravenous solution cartridge*
- *metronidazole in nacl intravenous solution 500-0.79 mg/100ml-%*
- MIACALCIN INJECTION
- *mitomycin intravenous*
- *mitoxantrone hcl intravenous concentrate 25 mg/12.5ml*
- MUSTARGEN
- *mycophenolate mofetil*
- *mycophenolate mofetil hcl*
- *mycophenolate sodium*
- NEBUPENT
- NEPHRAMINE
- NULOJIX
- *nutrilipid intravenous emulsion 20 %*
- *ondansetron*

- *ondansetron hcl injection solution 4 mg/2ml, 4 mg/2ml (2ml syringe)*
- *ondansetron hcl oral*
- *oxaliplatin intravenous solution 100 mg/20ml*
- *oxaliplatin intravenous solution reconstituted 100 mg*
- *paclitaxel intravenous concentrate 100 mg/16.7ml, 300 mg/50ml*
- *paricalcitol*
- *piperacillin sod-tazobactam so intravenous solution reconstituted 2.25 (2-0.25) gm*
- PREMASOL
- PROCALAMINE
- PROGRAF INTRAVENOUS
- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG
- PROSOL
- PULMOZYME
- RAPAMUNE ORAL SOLUTION
- RECOMBIVAX HB
- REMODULIN
- SANDIMMUNE ORAL
- SENSIPAR
- *sirolimus oral*
- SYNERCID
- *tacrolimus oral*
- TECENTRIQ
- TEFLARO
- TENIVAC
- *tetanus-diphtheria toxoids td*
- THYMOGLOBULIN
- *tigecycline*
- *tobramycin inhalation*
- *topotecan hcl intravenous solution reconstituted*
- TORISEL
- TRAVASOL
- TREANDA INTRAVENOUS SOLUTION RECONSTITUTED
- TREXALL
- TRISENOX INTRAVENOUS SOLUTION 12 MG/6ML
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- *vancomycin hcl intravenous solution reconstituted 10 gm, 1000 mg, 500 mg*
- VARUBI ORAL
- VENTAVIS
- *vinblastine sulfate intravenous solution*
- VINCASAR PFS
- *vincristine sulfate intravenous*
- *vinorelbine tartrate intravenous solution 50 mg/5ml*
- XATMEP
- ZEMAIRA
- ZORTRESS

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.

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