

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

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 or neurologist.
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

- *dalfampridine er*

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

ARIKAYCE

Products Affected

- ARIKAYCE

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 Mycobacterium avium complex infection and used as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with infectious disease specialist or pulmonologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
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

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

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], Tasigna [nilotinib], Sprycel [dasatinib] 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	Plan Year
Other Criteria	None

BRAFTOVI

Products Affected

- BRAFTOVI

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 documented BRAF V600E or V600K mutation as detected by an FDA-approved test used in combination with binimetinib
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

BRIVIACT

Products Affected

- BRIVIACT ORAL

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	18 years of age or older
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	Plan Year
Other Criteria	For renewal, Patient is benefiting from treatment (i.e., improvement in lung function [FEV1], decreased number of pulmonary exacerbations).

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	12 weeks
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, immunologist or allergist.
Coverage Duration	Plan Year
Other Criteria	None

COMETRIQ

Products Affected

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

COPIKTRA

Products Affected

- COPIKTRA

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: A) chronic lymphocytic leukemia OR B) small lymphocytic lymphoma OR C) Follicular lymphoma. Used in patients with history of 2 prior therapies
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	Plan Year
Other Criteria	None

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	Plan Year
Other Criteria	None

COSENTYX

Products Affected

- COSENTYX 300 DOSE
- COSENTYX SENSOREADY 300 DOSE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	None
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Failure, contraindication, or intolerance to Enbrel (etanercept) AND Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Cosentyx therapy. All indications (Initial, reauth): Patient is not receiving Cosentyx in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Cosentyx in combination with a Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]. For a diagnosis of PsA or plaque psoriasis, Patient is not receiving Cosentyx in combination with a phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)].
Age Restrictions	None
Prescriber Restrictions	Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS (Initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Plan year
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Cosentyx therapy.

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 AND documentation of combination therapy with vemurafenib.
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

****Under CMS Review****

DAURISMO

Products Affected

- DAURISMO

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) newly diagnosed acute myeloid leukemia in adults 75 years of age or older who have comorbidities that preclude use of intensive induction chemotherapy and used in combination with cytarabine
Age Restrictions	75 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
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	Diclofenac 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

ENBREL

Products Affected

- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis). Combined use with a biologic disease-modifying anti-rheumatic drugs or potent immunosuppressant (e.g., azathioprine or cyclosporine).
Required Medical Information	Diagnosis of moderate to severe rheumatoid arthritis and patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs for at least 3 consecutive months OR Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis and patient had an inadequate response, intolerance or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs) for at least 3 consecutive months OR Diagnosis of psoriatic arthritis and patient had an inadequate response, intolerance, or contraindication to methotrexate OR Diagnosis of ankylosing spondylitis and patient had an inadequate response, intolerance or contraindication to one or more NSAIDs OR Diagnosis of moderate to severe chronic plaque psoriasis (affecting more than 5% of body surface area or affecting crucial body areas such as the hands, feet, face, or genitals) and patient had an inadequate response, intolerance or contraindication to conventional therapy with at least one of the following: phototherapy (including but not limited to Ultraviolet A with a psoralen [PUVA] and/or retinoids [RePUVA] for at least one continuous month or one or more oral systemic treatments (i.e. methotrexate, cyclosporine, acitretin, sulfasalazine) for at least 3 consecutive months.
Age Restrictions	2 years of age or older for JIA or JRA. 4 years of age or older for plaque psoriasis. 18 years of age or older for all other indications
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	None

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	Plan year
Other Criteria	None

EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	None
Required Medical Information	Diagnosis of Lennox-Gastaut syndrome OR severe myoclonic epilepsy in infancy
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by or consultation with a neurologist
Coverage Duration	Plan Year
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.

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	Pulmonologist
Coverage Duration	Plan Year
Other Criteria	None

ESRD THERAPY

Products Affected

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

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

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	Plan Year
Other Criteria	None

FENTANYL ORAL

Products Affected

- *fentanyl citrate buccal*

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 two extended release oral opioids [e.g., Morphine Sulfate ER, Oxycodone HCL ER, or Methadone] or is unable to take extended release oral opioids secondary to inadequate response, allergy, adverse events, contraindications, swallowing difficulty, or uncontrollable nausea/vomiting.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Plan Year
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, immunologist or allergist.
Coverage Duration	Plan Year
Other Criteria	None

GALAFOLD

Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	None
Required Medical Information	Diagnosis of Fabry disease with an amenable galactosidase alpha gene (GLA) mutation
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	None

GILENYA

Products Affected

- GILENYA ORAL CAPSULE 0.5 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. Baseline QTc interval greater than or equal to 500 ms. Receiving concurrent treatment with Class Ia or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol).
Required Medical Information	Diagnosis of a relapsing form of multiple sclerosis or diagnosis of first clinical episode with MRI features consistent with MS AND Patient will be observed for signs and symptoms of bradycardia in a controlled setting for at least 6 hours after the first dose.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Initial - 6 months. Renewal - 12 months
Other Criteria	For renewal, the patient has experienced no or slowed disease progression.

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 from the physician in patients with: 1) metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test or 2) metastatic squamous NSCLC, progressing after 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

GLATIRAMER

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	Plan Year
Other Criteria	For renewal, patient has no or slowed disease progression.

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 in patients 6 years of age to 17 years of age.
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	None

HEPATITIS C

Products Affected

- MAVYRET
- *sofosbuvir-velpatasvir*
- VOSEVI

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 ALL GENOTYPES: Trial/failure, contraindication to, or intolerance to Mavyret is required prior to approval of Vosevi.
Age Restrictions	18 years of age and older
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

HRM - ANALGESICS

Products Affected

- ASCOMP-CODEINE
- *butalbital-apap-caff-cod oral capsule 50-325-40-30 mg*
- *indomethacin er*
- *indomethacin oral*
- *ketorolac tromethamine 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, 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 oral solution*
- *digoxin oral tablet 250 mcg*

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 (Digoxin 0.125mg dose, propranolol or sotalol for atrial fibrillation) 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 oral syrup*
- *hydroxyzine hcl oral tablet*
- *hydroxyzine pamoate oral*
- *promethazine hcl oral syrup*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal suppository 50 mg*
- *promethazine vc plain oral solution*
- *promethazine-phenylephrine*

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, levocetirizine. Part D coverage is not allowed if a hospice program drug benefit is available for the drug.

HRM - ANTIPARKINSON AGENTS

Products Affected

- *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 considered safe and effective in the elderly (i.e., haloperidol, quetiapine, risperidone, aripiprazole, asenapine, iloperidone, lurasidone, paliperidone, or ziprasidone) 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	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 1 of the alternative(s) (Alternatives for the following diagnoses include a) ANXIETY: citalopram, escitalopram, fluvoxamine, sertraline, duloxetine, venlafaxine, buspirone. b) INSOMNIA: 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 - 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

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	None

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
- *norethindrone-eth estradiol oral tablet 1-5 mg-mcg*
- 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, ibandronate, raloxifene. IF BEING USED TO TREAT Post-menopausal symptoms must try 2 of the safer alternatives: citalopram, fluoxetine, sertraline, venlafaxine. 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, ibandronate, raloxifene (zoledronic acid for bed-bound patients or for post-hip fracture). Vaginal Symptoms: 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 alternative 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 formulary alternative 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 doxepin (less than or equal to 6mg/d)

HRM - SKELETAL MUSCLE RELAXANTS

Products Affected

- *chlorzoxazone oral tablet 500 mg*
- *cyclobenzaprine 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 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

HUMIRA

Products Affected

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS PREFILLED SYRINGE KIT
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PS/UV/ADOL HS START
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis). Combined use with a biologic disease-modifying anti-rheumatic drugs or potent immunosuppressant (e.g., azathioprine or cyclosporine).
Required Medical Information	<p>Diagnosis of ONE of the following: A) moderate to severe rheumatoid arthritis OR moderate to severe polyarticular juvenile idiopathic arthritis and patient had inadequate response, intolerance, or contraindication to one or more non-biologic DMARDs for at least 3 consecutive months B) psoriatic arthritis and patient had inadequate response, intolerance, or contraindication to methotrexate C) ankylosing spondylitis and patient had inadequate response, intolerance, or contraindication to one or more NSAIDs D) moderate to severe chronic plaque psoriasis (affecting more than 5% of body surface area or affecting crucial body areas such as the hands, feet, face, or genitals) and patient had inadequate response, intolerance, or contraindication to conventional therapy with at least one of the following: phototherapy (including but not limited to UVA with a psoralen [PUVA] and/or retinoids [RePUVA] for at least one continuous month or one or more oral systemic treatments (Cyclosporine, acitretin, sulfasalazine, methotrexate, leflunomide, azathioprine) for at least 3 consecutive months E) moderate to severe Crohn's disease and patient had inadequate response, intolerance, or contraindication to conventional therapy with two or more of the following: corticosteroids or non-biologic DMARDs F) moderate to severe ulcerative colitis and patient had inadequate response, intolerance or contraindication to conventional therapy with two or more of the following: corticosteroids, 5-ASA (i.e. mesalamine, sulfasalazine, balsalazide) or non-biologic DMARDs (azathioprine, cyclosporine, hydroxychloroquine, leflunomide, sulfasalazine) G) non-infectious uveitis (including intermediate, posterior, and panuveitis) and patient had inadequate response, intolerance or contraindication to conventional therapy with one of the following: systemic or topical corticosteroids or ophthalmic antimuscarinics. OR H)</p>

PA Criteria	Criteria Details
	moderate to severe hidradenitis suppurativa.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Plan Year
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	Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor in postmenopausal women as initial endocrine-based therapy OR 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

IMATINIB

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 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

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

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

INJECTABLE ANTICOAGULANT

Products Affected

- *fondaparinux sodium*

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

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

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	Plan Year
Other Criteria	None

****Under CMS Review****

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	Patient meets one of the following conditions: A) Diagnosis of systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis) OR B) Diagnosis of onychomycosis confirmed by one of the following: positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy) OR C) patient has a diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole (ORAL SOLUTION ONLY).
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	Myelofibrosis: Diagnosis of primary myelofibrosis, OR post-polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND history of failure, contraindication, or intolerance to 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.

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 ivacaftor 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

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	KISQALI: Breast Cancer: A) Metastatic or advanced, HER-2 negative, hormone receptor-positive, postmenopausal women in combination with fulvestrant as initial endocrine based therapy or following disease progression on endocrine therapy, B) Metastatic or advanced, HER-2 negative, hormone receptor-positive, premenopausal, perimenopausal or postmenopausal women, in combination with an aromatase inhibitor for initial endocrine-based treatment. KISQALI FEMARA: HER-2 negative, hormone receptor-positive, advanced or metastatic breast cancer 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.

LENVIMA

Products Affected

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

PA Criteria	Criteria Details
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 advanced renal cell carcinoma following one prior anti-angiogenic therapy in combination with everolimus OR unresectable hepatocellular carcinoma
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 (intrauterine device) 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 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	For the FDA-labeled indication of post-herpetic neuralgia, no additional criteria are required to be met. For diabetic neuropathy: the patient must have had inadequate response or documented intolerance to duloxetine and Lyrica (pregabalin).

LINEZOLID

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

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

LORBRENA

Products Affected

- LORBRENA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Concomitant use with strong CYP3A4 inducers
Required Medical Information	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) in patients with disease progression on alectinib as the first ALK inhibitor therapy for metastatic disease, OR ceritinib as first ALK inhibitor therapy for metastatic disease, OR crizotinib and at least one other ALK inhibitor for metastatic disease.
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

LUPRON

Products Affected

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

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), C) Anemia due to uterine Leiomyomata (Fibroids) (3.75 mg 1-month & 11.25 mg 3-month depots only) and Patient is preoperative, D) Central precocious puberty (idiopathic or neurogenic) in children.
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 ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	None
Required Medical Information	Supporting statement with diagnosis of 1) deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer and have been treated with 3 or more prior lines of chemotherapy OR 2) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and have a complete or partial response to platinum-based chemotherapy OR 3) HER2-negative, deleterious or suspected deleterious germline BRCA mutated (gBRCAm) metastatic breast cancer and have been previously treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting.
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 mutation as detected by an FDA-approved test.
Age Restrictions	None
Prescriber Restrictions	Oncologist
Coverage Duration	Plan Year
Other Criteria	None

MEKTOVI

Products Affected

- MEKTOVI

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 documented BRAF V600E or V600K mutation as detected by an FDA-approved test used in combination with encorfenib
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

MIGLUSTAT

Products Affected

- *miglustat*

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

MODAFINIL

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

MS INTERFERONS

Products Affected

- AVONEX
- AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT
- AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT
- BETASERON SUBCUTANEOUS KIT
- PLEGRIDY
- PLEGRIDY STARTER PACK

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	Plan Year
Other Criteria	For renewal, patient has experienced an objective response to therapy (i.e. no or slowed progression of disease)

NATPARA

Products Affected

- NATPARA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	None
Required Medical Information	Diagnosis of hypocalcemia in patients with hypoparathyroidism.
Age Restrictions	None
Prescriber Restrictions	Prescriber is certified in the NATPARA REMS program
Coverage Duration	Plan Year
Other Criteria	None

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	Plan Year
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

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

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

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.

ORKAMBI

Products Affected

- ORKAMBI

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	None
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 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)

OXERVATE

Products Affected

- OXERVATE

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) Neurotrophic keratitis
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or optometrist
Coverage Duration	2 months
Other Criteria	None

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
SUBCUTANEOUS SOLUTION 180
MCG/0.5ML
- 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 a proteasome inhibitor

PROMACTA

Products Affected

- PROMACTA ORAL TABLET

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 or in combination with standard 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 75 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.

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

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

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 one of the following 1) multiple myeloma and medication will be used in combination with dexamethasone, 2) autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, 3) transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, 4) 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.

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	18 years of age or 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

SILDENAFIL

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

SIMPONI

Products Affected

- SIMPONI SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- SIMPONI SUBCUTANEOUS 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	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall) OR failure, contraindication, or intolerance to methotrexate (Rheumatrex/Trexall). One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi therapy. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Patient is corticosteroid dependent (ie, an inability to successfully taper corticosteroids without a return of the symptoms of UC), OR history of failure, contraindication, or intolerance to one of the following: oral aminosalicylate, oral corticosteroid, azathioprine, 6-mercaptopurine. One of the following: Failure, contraindication, or intolerance to Humira (adalimumab), OR for continuation of prior Simponi therapy. All indications (Initial, reauth): Patient is not receiving Simponi in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]. Patient is not receiving Simponi in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]. For a diagnosis of PsA, Patient is not receiving Simponi in combination with a phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)].
Age Restrictions	None
Prescriber Restrictions	RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. UC (Initial): Prescribed by or in consultation with a

PA Criteria	Criteria Details
	gastroenterologist.
Coverage Duration	UC (Initial): 12 weeks. UC (Reauth): 12 months. RA, AS, PsA (Initial, reauth): 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Simponi therapy.

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
Coverage	Approval will be 6 days for FDA labeled indications or 30 days for all

PA Criteria	Criteria Details
Duration	other indications
Other Criteria	None

SOMATULINE DEPOT

Products Affected

- SOMATULINE DEPOT MG/0.5ML, 60 MG/0.2ML, 90
SUBCUTANEOUS SOLUTION 120 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: 1) 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. 2) Unresectable, well- or moderately-differentiated, locally advanced or metastatic carcinoid gastroenteropancreatic neuroendocrine tumor (NET). 3) Carcinoid syndrome.
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	Diagnosis of one of the following: 1) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase, 2) Chronic, accelerated or 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, 4) Newly diagnosed Ph+ ALL in combination with chemotherapy
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan Year
Other Criteria	None

STELARA

Products Affected

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML
- STELARA SUBCUTANEOUS 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	Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. Plaque psoriasis (Initial): One of the following: a) History of failure, contraindication, or intolerance (F/C/I) to Enbrel (etanercept) and Humira (adalimumab) OR b) for continuation of prior Stelara therapy. PsA (Initial): One of the following: a) History of failure, contraindication, or intolerance (F/C/I) to Enbrel (etanercept) and Humira (adalimumab) OR b) for continuation of prior Stelara therapy. For Crohn's disease, history of failure, contraindication, or intolerance (F/C/I) to Humira (adalimumab).
Age Restrictions	None
Prescriber Restrictions	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	Plan year
Other Criteria	Reauthorization (all indications): Documentation of positive clinical response to Stelara therapy. All indications (initial, reauth): Patient is not receiving Stelara in combination with either of the following: Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Otezla (apremilast)] or a Janus Kinase Inhibitor [eg, Xeljanz (tofacitinib)]. Patient is not receiving Stelara in combination with a phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)].

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	Plan Year
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	Autoimmune hepatitis. Hepatic decompensation (Child-Pugh score greater than 6 [Class B or C]).
Required Medical Information	Melanoma: Diagnosis of melanoma with microscopic or gross nodal involvement AND The prescribed medication will be used as adjuvant therapy within 84 days of definitive surgical resection, including complete lymphadenectomy.
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

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

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	A documented positive BRAF V600E or V600K mutation as detected by an FDA-approved test
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

TAGRISO

Products Affected

- TAGRISO

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

TAKHZYRO

Products Affected

- TAKHZYRO

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 used for prophylaxis
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	None

TALZENNA

Products Affected

- TALZENNA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	None
Required Medical Information	Diagnosis of deleterious or suspected deleterious germline BRCA-mutated HER2-negative locally advanced or metastatic breast cancer
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

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	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.
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	Diagnosis of newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in the chronic phase OR Diagnosis of Ph+ CML with resistance or intolerance to prior therapy.
Age Restrictions	None
Prescriber Restrictions	Oncologist
Coverage Duration	Plan Year
Other Criteria	None

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

TECFIDERA

Products Affected

- TECFIDERA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting MS or progressive-relapsing MS, or secondary-progressive 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 had an objective response to therapy (i.e., no or slowed progression of disease)

TEGSEDI

Products Affected

- TEGSEDI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	One of the following A) Platelet count below 100 x 10 ⁹ /L B) documented history of acute glomerulonephritis caused by inotersen
Required Medical Information	Diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis AND patient is enrolled in Tegsedi REMS program
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Plan year
Other Criteria	None

TESTOSTERONES

Products Affected

- *testosterone transdermal gel 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 40.5 mg/2.5gm (1.62%)*

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Female, prostate cancer, or breast cancer.
Required Medical Information	Before the start of testosterone therapy patient has (or patient currently has) a confirmed low testosterone level (i.e., total testosterone less than 300 ng/dL, free or bioavailable testosterone less than 5 ng/dL) or absence of endogenous testosterone.
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	Prescribed by or in consultation with an oncologist or infectious disease specialist.
Coverage Duration	Plan Year
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.

TIBSOVO

Products Affected

- TIBSOVO

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 myeloid leukemia in relapsed or refractory patients, with susceptible isocitrate dehydrogenase-1 mutation
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

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

TRIENTINE

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

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

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) 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

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

VITRAKVI

Products Affected

- VITRAKVI

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) Solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have no satisfactory alternative treatments or that have progressed following treatment
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an Oncologist
Coverage Duration	Plan year
Other Criteria	None

VIZIMPRO

Products Affected

- VIZIMPRO

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 non-small cell lung cancer with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a 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	Diagnosis of advanced/metastatic renal cell carcinoma OR Diagnosis of advanced soft tissue sarcoma and patient received at least one prior chemotherapy (e.g., doxorubicin, dacarbazine, ifosfamide, epirubicin, docetaxel, or vinorelbine).
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	None

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

XELJANZ

Products Affected

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	None
Required Medical Information	Psoriatic arthritis (PsA) or Rheumatoid arthritis (RA) (Initial): Diagnosis of psoriatic arthritis or moderately to severely active RA and an inadequate response or intolerance to methotrexate. One of the following: Failure, contraindication, or intolerance to Enbrel (etanercept) OR Humira (adalimumab), OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy. Patient is not receiving tofacitinib in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine). Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Patient is corticosteroid dependent (ie, an inability to successfully taper corticosteroids without a return of the symptoms of UC), OR history of failure, contraindication, or intolerance to one of the following: oral aminosalicylate, oral corticosteroid, azathioprine, 6-mercaptopurine AND one of the following: failure, contraindication, or intolerance to Humira (adalimumab).
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or gastroenterologist.
Coverage Duration	Plan Year
Other Criteria	Reauthorization: Documentation of positive clinical response to tofacitinib therapy. Patient is not receiving tofacitinib in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (e.g., azathioprine,

PA Criteria	Criteria Details
	cyclosporine).

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

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 1300 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

XOSPATA

Products Affected

- XOSPATA

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 presence of FLT3 mutation as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	Plan year
Other Criteria	None

XTANDI

Products Affected

- XTANDI

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 castration-resistant prostate cancer AND the patient has tried and had an inadequate response, contraindication or intolerance to Zytiga.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed or in consultation with an oncologist or urologist
Coverage Duration	Plan Year
Other Criteria	None

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

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	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

PART B VERSUS PART D

Products Affected

- ABELCET
- *acetylcysteine inhalation*
- *acyclovir sodium intravenous solution*
- *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*
- *aprepitant*
- ASTAGRAF XL
- AZASAN
- *azathioprine oral*
- BIVIGAM INTRAVENOUS SOLUTION 10 GM/100ML
- *budesonide inhalation*
- *calcitonin (salmon)*
- *calcitriol oral*
- CARIMUNE NF INTRAVENOUS SOLUTION RECONSTITUTED 6 GM
- *casprofungin acetate*
- *chlorpromazine hcl oral tablet 10 mg, 25 mg*
- CLINIMIX E/DEXTROSE (2.75/10)
- CLINIMIX E/DEXTROSE (2.75/5)
- CLINIMIX E/DEXTROSE (4.25/10)
- CLINIMIX E/DEXTROSE (4.25/25)
- CLINIMIX E/DEXTROSE (4.25/5)
- CLINIMIX E/DEXTROSE (5/15)
- CLINIMIX E/DEXTROSE (5/20)
- CLINIMIX/DEXTROSE (4.25/10)
- CLINIMIX/DEXTROSE (4.25/25)
- CLINIMIX/DEXTROSE (4.25/5)
- CLINIMIX/DEXTROSE (5/15)
- CLINIMIX/DEXTROSE (5/20)
- CLINIMIX/DEXTROSE (5/25)
- *cromolyn sodium inhalation*
- *cyclophosphamide oral capsule*
- *cyclosporine modified*
- *cyclosporine oral capsule*
- *daptomycin*
- DEPO-PROVERA INTRAMUSCULAR SUSPENSION 400 MG/ML
- *diphtheria-tetanus toxoids dt*
- *doripenem intravenous solution reconstituted 500 mg*
- *duramorph*
- ENGERIX-B INJECTION SUSPENSION 10 MCG/0.5ML, 20 MCG/ML
- FLEBOGAMMA DIF INTRAVENOUS SOLUTION 5 GM/50ML
- *fluconazole in sodium chloride intravenous solution 200-0.9 mg/100ml-%, 400-0.9 mg/200ml-%*
- FREAMINE HBC
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- GENGRAF ORAL CAPSULE 100 MG, 25 MG
- GENGRAF ORAL SOLUTION
- *granisetron hcl oral*
- HEPATAMINE
- IMOVAX RABIES
- INTRON A
- *ipratropium bromide inhalation*
- *ipratropium-albuterol*
- *methotrexate oral*
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
- *methotrexate sodium injection solution 250 mg/10ml*
- *metronidazole in nacl intravenous solution 500-0.79 mg/100ml-%*

- *mycophenolate mofetil*
- *mycophenolate sodium*
- NEBUPENT
- NEPHRAMINE
- *nutrilipid intravenous emulsion 20 %*
- *ondansetron*
- *ondansetron hcl oral*
- *paricalcitol oral*
- *piperacillin sod-tazobactam so intravenous solution reconstituted 2.25 (2-0.25) gm*
- PREMASOL
- PROCALAMINE
- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG
- PROSOL
- PULMOZYME
- RAPAMUNE ORAL SOLUTION
- RECOMBIVAX HB
- SANDIMMUNE ORAL SOLUTION
- SENSIPAR
- *sirolimus oral*
- *tacrolimus oral*
- TEFLARO
- TENIVAC
- *tetanus-diphtheria toxoids td*
- *tigecycline*
- *tobramycin inhalation*
- TRAVASOL
- TREXALL
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- *vancomycin hcl intravenous solution reconstituted 1 gm, 10 gm, 1000 mg, 250 mg, 500 mg, 750 mg*
- VARUBI ORAL
- XATMEP
- 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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