ACITRETIN

Products Affected

- acitretin

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have severe disease. Must have adequate trial of methotrexate or cyclosporine with inadequate response or significant side effect/toxicity or have a contraindication to these therapies.
Age Restrictions	Age 18 years or older.
Prescriber Restrictions	Dermatologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ACNE PRODUCTS

Products Affected

- adapalene topical cream
- adapalene topical gel 0.1 %
- Avita topical cream
- Tazorac
- tretinoin topical cream
- tretinoin topical gel 0.01 %, 0.025 %

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Diagnoses not covered: solar elastosis, sun damage, wrinkles, actinic damage, melasma, lentigines / freckles (hyperpigmented macules, liver spots), heliodermatosis, dermatoheliosis
Required Medical Information	Diagnosis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

ACTEMRA

Products Affected

- Actemra intravenous
- Actemra subcutaneous

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with tocilizumab.
Required Medical Information	Diagnosis. Negative tuberculosis skin test prior to use of tocilizumab. Baseline AST and ALT labs less than 1.5x upper limit of normal, ANC greater than 2000 cells per cubic mm, platelet count greater than 100,000 cells per cubic mm. For RA and polyarticular JIA (PJIA): must have moderately to severely active disease and must have adequate trials of etanercept and adalimumab with inadequate responses or significant side effects/toxicities unless contraindicated. For active systemic JIA (SJIA): must have active disease (defined as active fever, active arthritis, OR erythrocyte sedimentation rate or C-reactive protein level greater than 2x upper limit of normal), must have chart documentation of clinical work-up to rule out other diagnoses and rationale for diagnosis and exclusion of other diagnoses (including all of the following: history of fever for at least 2 weeks, history of arthritis in 1 more more joints, and history of at least one of the following: erythematous rash, generalized lymph node enlargement, hepatomegaly or splenomegaly, or pericarditis, pleuritis, or peritonitis), must have adequate trial of methotrexate with inadequate response or significant side effects or toxicity unless there is a contraindication when there is active arthritis OR must have adequate trial of 1 NSAID and 1 corticosteroid with inadequate response or significant side effects or toxicity unless there is a contraindication when there are active systemic features such as rash and fever. For reauth: improvement in condition, AST and ALT labs less than or equal to 5x upper limit of normal, ANC greater than or equal to 500 cells per cubic mm, and platelet count greater than or equal to 50,000 cells per cubic mm.
Age Restrictions	RA: age 18 years and older. JIA: age 2 years and older
Prescriber Restrictions	RA, poylarticular JIA: rheumatologist. Systemic JIA: pediatric rheumatologist.
Coverage Duration	365 Days

PA Criteria	Criteria Details
Other Criteria	Not Applicable

ACTHAR

Products Affected

- Acthar H.P.

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For infantile spasms: EEG confirming diagnosis of infantile spasms. For following diagnoses where IV steroid trial(s) required: examples include methylprednisolone acetate, methylprednisolone sodium succinate, and triamcinolone acetonide, all of which have FDA-approval for use in these diagnoses. For MS: must be experiencing acute exacerbation of MS and have adequate trial of 2 IV steroids w/ inadequate response or significant side effects/toxicity. For severe erythema multiforme (Stevens-Johnsons Syndrome), serum sickness, severe acute or chronic allergic or inflammatory processes involving eye and its adnexa (e.g. keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroditis, optic neuritis, chorioretinitis, anterior segment inflammation), symptomatic sarcoidosis: must have adequate trial of 2 IV steroids w/ inadequate response or significant side effects/toxicity. For RA (incl. Juvenile RA), psoriatic arthritis, ankylosing spondylitis: must be using as adjunctive therapy for short-term administration (to tide over an acute episode or exacerbation) and have adequate trial of 2 IV steroids w/ inadequate response or significant side effects/toxicity. For systemic lupus erythematosis, dermatomyositis (polymyositis): may be used during exacerbation or as maintenance therapy and must have adequate trial of 2 IV steroids w/ inadequate response or significant side effects/toxicity. For nephrotic syndrome: must be used to induce diuresis or remission of proteinuria, must be experiencing acute exacerbation of nephrotic syndrome, must have adequate trial of 1 IV steroid w/ inadequate response or significant side effect/toxicity AND 1 cytotoxic/immunosuppressive medication (e.g. cyclophosphamide, cyclosporine, mycophenolate) w/ inadequate response or significant side effect/toxicity unless contraindicated. For reauth: must have documentation from prescriber describing initial response to therapy and need for continuation or retreatment.
Age Restrictions	Infantile spasms: age 2 years or younger. MS: age 18 years or older.
Prescriber Restrictions	Infantile spasm: pediatric neurologist. MS: neurologist. RA, Psoriatic Arthritis, Ankylosing Spondylitis: rheumatologist. Lupus,

PA Criteria	Criteria Details
	dermatomyositis: dermatologist or rheumatologist. Eye dx: ophthamologist. Nephrotic syndrome: nephrologist. All other dx: no prescriber restrictions.
Coverage Duration	30 days
Other Criteria	Not Applicable

ACTIMMUNE

Products Affected

- Actimmune

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Diagnoses not covered: basal cell carcinoma of the skin, breast cancer, burn infection, Chronic Myeloid Leukemia, condyloma acuminatum, graft vs. host disease, idiopathic pulmonary fibrosis, kaposi's Sarcoma, malignant mesothelioma, mycobacteriosis, ovarian cancer, rheumatoid arthritis, scleroderma, chronic hepatitis B, Whipple's disease
Required Medical Information	Diagnosis. For severe malignant osteopetrosis: must have diagnosis confirmed by radiological evidence.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	For chronic granulomatous disease: by or in consultation with immunologist, hematologist, rheumatologist, or infectious disease physician. For severe malignant osteopetrosis: by or in consultation with orthopedic surgeon, hematologist, or endocrinologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

ACUTE HAE

Products Affected

- Berinert intravenous kit
- Firazyr
- Ruconest

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of HAE confirmed by following laboratory values on 2 separate instances (copy of laboratory reports required, must include reference ranges): low C4 complement level in mg/dL, normal C1q complement component level in mg/dL (C1q complement component level not required for patients under age of 18 or patients whose symptoms began before age 18), and either low C1 esterase inhibitor antigenic level in mg/dL or low C1 esterase inhibitor functional level expressed as a percent. Must have chart documentation indicating member has received at least one dose of requested product as treatment for HAE attack in past, responded to medication, and was able to tolerate medication. For reauth, must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or under the direction of a HAE specialist (defined as an allergist/immunologist who attests to clinical experience in HAE).
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	If clinical documentation confirms the required criteria, Firazyr will be approved after consultation with a Medical Director.

ADAGEN

Products Affected

- Adagen

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have failed or not be a candidate for bone marrow transplantation. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or less
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

ADCIRCA

Products Affected

- Adcirca

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Current use of nitrate product
Required Medical Information	Diagnosis of PAH (WHO Group I) confirmed diagnosis by right heart catheterization. Must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than or equal to 25 mmHg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than 3 Wood units. Must have WHO Functional Class II-IV symptoms. Must have inadequate response or intolerance to sildenafil (Revatio). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Cardiologist or pulmonologist. Combination therapy with two or more PAH agents must be prescribed by or in consultation with a pulmonary hypertension specialist.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

ADEFOVIR

Products Affected

- adefovir

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Hepatitis B Virus Drug Resistance panel showing resistance to prior tx w/ adefovir
Required Medical Information	Diagnosis. Must have documentation of results of Hep B Virus Drug Resistance panel if previously received antiviral tx regimen for Hep B. Must have documentation of baseline eval and results for following tests: Hep B virus (HBV) DNA viral load, hepatitis B e antigen (HBeAg), antibody to hepatitis B e antigen (anti-HBe), hepatitis B surface antigen (HBsAg), antibody to hepatitis surface antigen (anti-HBs), liver biopsy (if available), alanine aminotransferase (ALT) level and assay reference range. Must have an adequate trial of Baraclude with inadequate response, significant side effect/toxicity, contraindication, or documented viral resistance to Baraclude or have clinical rationale to support use of adefovir over Baraclude. For reauth: must have doc from prescriber indicating continued benefit from tx, doc of recent HBV DNA level, chart doc of HBV Drug Resistance panel if mbr has evidence of virologic breakthrough (greater than 10-fold increase in serum HBV DNA from nadir during tx in mbr who had initial virologic response), and doc of HBeAg/Anti-HBe/HBsAg/Anti-HBs (for mbrs with HBeAg positive and for mbrs with HBeAg negative not falling under any other indications).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Infectious disease physician, gastroenterologist, hepatologist, or transplant physician
Coverage Duration	365 days or until disease progression or clearance
Other Criteria	Regimens/requirements based upon AASLD Practice Guidelines for Chronic Hepatitis B. For HBeAg+ chronic HBV: must meet 1 ALT criterion (ALT greater than or equal to 2xULN OR evidence of moderate/severe inflammation or signif. fibrosis on biopsy) and have HBV DNA level greater than 20,000 IU/mL (not required for pediatric patients if ALT greater than or equal to 2xULN for longer than 6 months). For HBeAg- chronic HBV: must meet 1 ALT criterion (ALT greater than or equal to 2xULN, ALT greater than 1xULN w/ evidence of

PA Criteria	Criteria Details
	moderate/severe inflammation or signif. fibrosis on biopsy, ALT less than or equal to ULN w/ ALT increased over time) and 1 HBV DNA criterion (HBV DNA greater than 20,000 IU/mL, HBV DNA greater than 2,000 IU/mL w/ evidence of moderate/severe inflammation or signif. fibrosis on biopsy, HBV DNA less than or equal to 2,000 IU/mL w/ HBV DNA increased over time). For cirrhosis w/ HBV: must have HBV DNA greater than 2,000 IU/mL OR detectable HBV DNA level w/ elevated ALT. For HBV mbr who had liver txfr for HBV or who received solid organ txfr from HBV+ donor: approve regardless of HBV DNA and ALT levels. For HBV carrier who needs immunosuppressive or cytotoxic tx: must be HBsAg+, have planned course of cancer chemotx or immunosuppressive tx. Reauth for HBeAg+: approve x1 year until all of following are met (loss of HBeAg, undetectable serum HBV DNA, completed 6-12 months of additional tx after appearance of anti-HBe. Reauth for HBeAg-: approve x1 yr until loss of HBsAg. Reauth for cirrhosis, for liver txfr for HBV, or for solid organ txfr from HBV+ donor: long-term tx approvable. Reauth for HBV carriers receiving immunosuppressive or cytotoxic tx: mbr w/ baseline HBV DNA less than 2,000 IU/mL should continue x6 months after completion of chemotx or immunosuppressive tx, mbr w/ baseline HBV DNA greater than 2,000 IU/mL should continue until reach therapeutic endpoints for immunocompetant HBV as listed above.

ADEMPAS

Products Affected

- Adempas

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Current use of nitrate product or phosphodiesterase inhibitor (i.e. sildenafil or tadalafil).
Required Medical Information	Diagnosis. Must have baseline negative pregnancy test prior to initiation of riociguat (if a female of childbearing potential). For PAH (WHO Group I), must have diagnosis confirmed by right heart catheterization, must have inadequate response or intolerance to sildenafil (Revatio), AND must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than or equal to 25 mmHg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than 3 Wood units. For reauth: must have chart documentation from prescriber indicating improvement in condition. For CTEPH (WHO Group 4), must be refractory to surgical treatment (i.e. pulmonary endarterectomy) or have inoperable CTEPH, must have chart documentation showing CTEPH confirmed through ventilation-perfusion scanning or pulmonary angiography AND a right heart catheterization that indicates the following hemodynamic values at least 90 days after start of full anticoagulation or 180 days after pulmonary endarterectomy unless there is clinical evidence of right heart failure and pulmonary hypertension on clinical exam and echocardiogram: mean pulmonary arterial pressure greater than 25mmHg and pulmonary vascular resistance greater than 3 Wood units. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Cardiologist or pulmonologist. Combination therapy with two or more PAH agents must be prescribed by or in consultation with a pulmonary hypertension specialist.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

AFINITOR

Products Affected

- Afinitor Disperz
- Afinitor oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

AFREZZA

Products Affected

- Afrezza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Concomitant chronic lung disease, such as asthma or COPD.
Required Medical Information	Diagnosis. Must require mealtime insulin and must be used in combination with long-acting insulin if diabetes type 1. Must have chart documentation of baseline pulmonary function testing. Must have chart documentation of an adequate trial of injectable rapid-acting insulin (e.g. Humalog, Novolog) with an inadequate response demonstrated by inadequately controlled blood glucose levels despite dose titration, as well as relevant written documentation of laboratory and/or objective values [e.g., blood glucose levels, physician progress notes, or Subjective, Objective, Assessment, and Plan (SOAP note) information representing the physician's interaction with the member] and clinical rationale explaining why injectable rapid-acting insulin has not produced the same clinical results as would be expected with the use of Afrezza. For reauth: must have documentation from prescriber indicating improvement in condition and confirming the member's pulmonary function is being monitored while on therapy.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

ALDURAZYME

Products Affected

- Aldurazyme

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 6 months or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

ALECENSA

Products Affected

- Alecensa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming ALK mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ALOSETRON

Products Affected

- alosetron

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Male gender. Constipation. Anatomical or biochemical abnormalities of the gastrointestinal tract. Concomitant use of fluvoxamine. History of chronic or severe constipation or sequelae from constipation, intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state, Crohn's disease or ulcerative colitis, diverticulitis, severe hepatic impairement.
Required Medical Information	Diagnosis. Must have chronic IBS symptoms. Must have chart documentation of how diagnosis was confirmed. Must have adequate trial of loperamide AND an antispasmodic (e.g. dicyclomine) with inadequate response or significant side effect/toxicity or have a contraindication. For reauth: must have documentation from prescriber indicating improvement in condition and no evidence of constipation or ischemic colitis.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Gastroenterologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

ALPHA1-PROTEINASE INHIBITORS

Products Affected

- Aralast NP intravenous recon soln 500 mg
- Glassia
- Prolastin-C
- Zemaira

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Confirmed diagnosis of congenital alpha1-antitrypsin deficiency with clinically evident emphysema or airflow obstruction. Alpha1-antitrypsin phenotype of PI*ZZ, PI*ZNull or PI*NullNull. Baseline (pretreatment) serum alpha1-antitrypsin concentration of less than 11 micromol/L as documented by either of the following: less than 50mg/dL as determined by nephelometry OR less than 80mg/dL as determined by radial immunodiffusion. Must not have selective IgA deficiencies with known antibodies against IgA (anti-IgA antibodies). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with a pulmonologist
Coverage Duration	365 Days
Other Criteria	Not Applicable

AMITIZA

Products Affected

- Amitiza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Known or suspected mechanical gastrointestinal obstruction.
Required Medical Information	Diagnosis. For chronic idiopathic constipation and irritable bowel syndrome with constipation: must have chart documentation of how diagnosis was confirmed and must have a trial and failure of lactulose and linaclotide (Linzess) with inadequate responses or significant side effect/toxicities or have a contraindication to these therapies. For opioid-induced constipation (OIC): must have documentation of current and ongoing opioid therapy and must have a trial and failure of lactulose and naloxegol (Movantik) with inadequate responses or significant side effect/toxicities or have a contraindication to these therapies. For reauth for all diagnoses: must have documentation from prescriber indicating improvement in condition (as demonstrated by an increase in the number of weekly stools from baseline). Additionally, for reauth for OIC: must continue to be on opioid therapy.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

AMPYRA

Products Affected

- Ampyra

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Moderate to severe renal impairment (CrCl less than or equal to 50mL/min), history of seizure, on concomitant therapy with other forms of 4-aminopyridine.
Required Medical Information	Diagnosis. Chart documentation of baseline motor disability or dysfunction. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Neurologist or Physical Medicine and Rehabilitation physician in consultation with the member's treating Neurologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

ANADROL

Products Affected

- Anadrol-50

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Carcinoma of breast or prostate in male patients. Carcinoma of breast in female patients with hypercalcemia. Pregnancy. Nephrosis (i.e. nephrotic phase of nephritis). Severe hepatic dysfunction.
Required Medical Information	Diagnosis. Anemia must be due to deficient red cell production (e.g. acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, hypoplastic anemia). For reauth: must have documentation from prescriber indicating improvement or stabilization in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Hematologist or oncologist
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

ANDROGENS

Products Affected

- Androderm
- AndroGel transdermal gel in metered-dose pump 20.25 mg/1.25 gram (1.62 %)
- AndroGel transdermal gel in packet 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)
- methyltestosterone oral capsule
- Striant
- Testim
- testosterone cypionate
- testosterone enanthate
- testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %)
- testosterone transdermal gel in packet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. For methyltestosterone, treatment of females with inoperable breast cancer is covered.
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Repeated morning serum total testosterone level less than 300ng/dL.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

APOKYN

Products Affected

- APOKYN

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Concomitant therapy with 5-HT3 antagonist (e.g. ondansetron)
Required Medical Information	Diagnosis. Must be on concomitant therapy with carbidopa/levodopa AND one of the following numbered options: (1)a dopamine agonist (e.g. ropinirole or pramipexole), (2)a monoamine oxidase-B inhibitor (e.g. rasagiline or selegiline), or (3)a catechol O-methyltransferase inhibitor (e.g. entacapone). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Neurologist
Coverage Duration	365 days
Other Criteria	Not Applicable

APTIOM

Products Affected

- Aptiom

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have had an inadequate response or intolerance to 2 generic antiepileptic drugs (e.g., oxcarbazepine, carbamazepine, lamotrigine, valproic acid, levetiracetam, zonisamide. If using eslicarbazepine as adjunctive therapy to other antiepileptic drugs, cannot be used with oxcarbazepine. Must have documentation of baseline transaminase and bilirubin levels.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with a neurologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ARANESP

Products Affected

- Aranesp (in polysorbate) injection solution 100 mcg/mL, 200 mcg/mL, 25 mcg/mL, 300 mcg/mL, 40 mcg/mL, 60 mcg/mL
- Aranesp (in polysorbate) injection syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Uncontrolled hypertension, known hypersensitivity to active substance or any excipients of product.
Required Medical Information	Diagnosis. Must have Hgb less than 10g/dL. For anemia due to chemotx for nonmyeloid malignancy: must have documentation of a minimum of 2 more months of chemotx planned. All dx: Must have iron status evaluated before and during treatment with EPO. Reauth for CKD on dialysis: must have Hgb less than 11g/dL. Reauth for CKD not on dialysis: must have Hgb less than 10g/dL. Reauth for anemia due to chemotx for nonmyeloid malignancy: must have Hgb less than 12g/dL and documentation of a minimum 2 more months of chemotx planned. Reauth for other dx: must have Hgb less than 12g/dL.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a nephrologist, hematologist/oncologist, or transplant physician
Coverage Duration	Initial: 90 days. Reauth: 90 days for chemotx, 180 days for other dx.
Other Criteria	Part B versus Part D determination will made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an ESRD-related condition. If the drug is determined not to be ESRD-related, criteria apply.

ARCALYST

Products Affected

- Arcalyst

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with rilonacept.
Required Medical Information	Diagnosis. Negative tuberculosis skin test, baseline lipid panel assessment. For Muckle-Wells: must have chart doc of diagnosis confirmed by genetic test (must have documentation of lab result confirming mutation in NLRP3 gene) or a clinical diagnosis (must have 3 of following: autosomal dominant pattern of disease inheritance, presence of severe fatigue, presence of musculoskeletal symptoms, presence of ocular symptoms, presence of erythematous rash, duration of most febrile episodes lasting greater than 24 hours, presence of amyloidosis, presence of hearing loss). For Familial Cold Autoinflammatory Syndrome: must have chart doc of diagnosis confirmed by genetic test (must have documentation of lab result confirming mutation in NLRP3 gene) or a clinical diagnosis (must have 4 of following: recurrent intermittent episodes of fever and rash that primarily follow natural/experimental/both types of generalized cold exposures, autosomal dominant pattern of disease inheritance, age of onset less than 6 months of age, duration of most attacks less than 24 hours, presence of conjunctivitis associated with attacks, absence of deafness/periorbital edema/lymphadenopathy/serositis). For reauth: must have documentation from prescriber indicating improvement in condition and assessment of lipid panel within 3 months (1st reauth) and regularly thereafter.
Age Restrictions	Age 12 years or older
Prescriber Restrictions	Rheumatologist, dermatologist, immunologist, or genetic specialist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

ARIPIPRAZOLE

Products Affected

- aripiprazole oral tablet,disintegrating 10 mg, 15 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For Major Depressive Disorder without psychosis, must have adequate trial and failure or inadequate response, duration of at least 4 weeks, or intolerance to monotherapy with 2 different antidepressant therapies (e.g. SSRIs or SNRIs) and must be on concomitant therapy with an SSRI or SNRI as adjunctive treatment (which can include medication from monotherapy trial above)
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

ARMODAFANIL

Products Affected

- armodafinil

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of sleep study confirming diagnosis for narcolepsy and OSA. Must have adequate trial of modafinil with an inadequate response OR have had a significant side effect/toxicity to modafinil. For narcolepsy: must have adequate trial and failure of CNS stimulant (e.g. amphetamine salts, dextroamphetamine, methylphenidate). For shift-work sleep disorder (SWSD), must meet International Classification of Sleep Disorders criteria for SWSD (either primary complaint of excessive sleepiness or insomnia temporarily associated w/ work period that occurs during habitual sleep phase OR polysomnography and Multiple Sleep Latency Test demonstrate loss of normal sleep-wake pattern, no other medical or mental disorders account for symptoms, and symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness such as time zone change syndrome) and must provide chart documentation of shift work schedule showing 5 or more night shifts per month (defined as at least 4 hours of shift occurring between 10pm and 8am). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	SWSD: 180 days. Narcolepsy, OSA: 365 days.
Other Criteria	Not Applicable

AUBAGIO

Products Affected

- Aubagio

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Members who are pregnant. Severe hepatic impairment. Evidence of infection. Treatment currently with antineoplastic, immunosuppressive, or immune modulating therapies.
Required Medical Information	Diagnosis of relapsing form of multiple sclerosis (MS). Negative tuberculosis skin test. For females, baseline negative pregnancy test with date prior to starting teriflunomide (if a female of childbearing potential). Recent (within 6 months) transaminase, bilirubin, CBC. Must previously have had inadequate response or intolerance to one other medication used to treat MS (e.g. dimethyl fumarate, glatiramer, or an interferon product such as Avonex or Plegridy). For reauth, documentation from provider showing disease has improved or stabilized while on therapy, monitoring of transaminase and bilirubin.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

BANZEL

Products Affected

- Banzel

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of Lennox-Gastaut Syndrome. Must have had an inadequate response or intolerance to 2 generic antiepileptic drugs (e.g. lamotrigine, topiramate, felbamate) and be using rufinamide as adjunctive therapy to other antiepileptic drugs (which can include medication from trial above).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a neurologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

BARBITURATES

Products Affected

- phenobarbital

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

BENLYSTA

Products Affected

- Benlysta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Severe active lupus nephritis or severe active central nervous system lupus. Evidence of infection. On concomitant therapy with biologic therapies, including B-cell targeted therapies, or IV cyclophosphamide.
Required Medical Information	Diagnosis of systemic lupus erythematosus. Must be auto-antibody positive, as evidenced through documentation of having one of the following laboratory markers: positive antinuclear antibodies titre greater than or equal to 1:80 or anti-double stranded DNA greater than or equal to 30 IU/mL. Must have adequate trial of hydroxychloroquine, azathioprine, methotrexate, or mycophenolate with inadequate response or signficant side effect/toxicity or have a contraindication to these therapies. Must be on concomitant therapy with any of the following (alone or in combination): corticosteroids, antimalarials, NSAIDS, and/or immunosuppressants. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Rheumatologist
Coverage Duration	Initial 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

BOSULIF

Products Affected

- Bosulif oral tablet 100 mg, 500 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

BOTOX

Products Affected

- Botox injection recon soln 100 unit, 200 unit

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For axillary hyperhidrosis: must have trial of 10-20% topical aluminum chloride with inadequate response or adverse effect of severe rash. For migraine: must have diagnosis of chronic migraine (defined as headache occurring 15 or more days per month for at least 3 consecutive months, 8 or more of total headache days per month each having been migraine or probable migraine days, and having at least 4 distinct headache episodes lasting at least 4 hours per day or longer), must not be using opioids for more than 10 days per month, and must have adequate trial of 1 month each of 2 prophylactic classes (e.g. anticonvulsants, beta-blockers, tricyclic antidepressants) with inadequate response. For urinary incontinence: must have trial of anticholinergic medication (e.g. oxybutynin, trospium, tolterodine, etc.) with inadequate response or side effects/toxicity or have a contraindication. For OAB w/ urge urinary incontinence, urgency, frequency: must have greater than 3 urinary urgency incontinence episodes in a 3-day period, greater than 8 micturitions per day, chart doc of specific examples of how quality of life impacted (e.g. sleep disturbance, work disruption, decrease in social interaction), and a trial (4 weeks) at recommended dose of 2 anticholinergic meds with inadequate response or intolerance unless contraindicated. For migraine reauth: must have documentation of decrease in frequency and/or severity of headaches per headache journal as a result of therapy. For OAB reauth: must have documentation of at least 2 urinary incontinence episodes in a 3-day period to support continuation. For reauth for all other dx: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Blepharospasm: age of at least 12 years. Chronic migraines: age 18 years or older.
Prescriber Restrictions	Hyperhidrosis: dermatologist. Chronic migraines: neurologist. OAB: urologist, fellowship-trained urogynecologist.
Coverage Duration	Initial: 90 days. Reauth: 180 days for OAB, 365 days for all other dx.

PA Criteria	Criteria Details
Other Criteria	Not Applicable

BRIVIACT

Products Affected

- Briviact

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have had an inadequate response or intolerance to two other antiepileptic drugs. Must have an evaluation by a psychiatrist and be followed concurrently by a psychiatrist if the member has a history of psychiatric symptoms including anger, aggression, hostility, irritability, suicidal ideation, and homicidal ideation OR if the member is currently undergoing psychiatric treatment. Must be using as adjunctive therapy to other anti-epileptic medications (which can include medications from trials above).
Age Restrictions	Age 16 years or older
Prescriber Restrictions	By or in consultation with a neurologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

CABOMETYX

Products Affected

- Cabometyx oral tablet 20 mg, 40 mg, 60 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have documentation of prior anti-angiogenic therapy.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with an oncologist or hematologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

CAPRELSA

Products Affected

- Caprelsa oral tablet 100 mg, 300 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

CARBAGLU

Products Affected

- Carbaglu

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Confirmed diagnosis of one of the following deficiencies: N-acetylglutamate synthase (NAGS), N-acetylglutamate (NAG), or carbamoyl phosphate synthetase 1 (CPS 1). Must have chart documentation describing how diagnosis was confirmed (e.g. genetic testing results, enzyme assays, ammonia levels, progress notes, etc.). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a physician who specializes in the treatment of inherited metabolic disorders.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

CERDELGA

Products Affected

- Cerdelga

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	On concomitant therapy with a CYP2D6 inhibitor (e.g. paroxetine) and a strong or moderate CYP3A inhibitor (e.g. ketoconazole) if a CYP2D6 extensive or intermediate metabolizer. On concomitant therapy with a strong CYP3A inhibitor (e.g. ketoconazole) if a CYP2D6 intermediate or poor metabolizer. CYP2D6 ultra-rapid metabolizer.
Required Medical Information	Diagnosis of mild to moderate Type I Gaucher disease with any of the following: hepatomegaly (defined as liver size greater than or equal to 1.25 times normal), splenomegaly (defined as spleen size greater than 0.2% of body weight), bone disease (defined as having one of the following: avascular necrosis, erlenmeyer flask deformity, lytic disease, marrow infiltrations, osteopenia, osteosclerosis, pathological fracture, or radiological evidence of joint deterioration), or bone marrow disease (defined as having anemia or thrombocytopenia). Must not have enzyme replacement therapy as therapeutic option (e.g. allergy/hypersensitivity to ERT, poor venous access, difficulties w/ infusion). Must have chart documentation of FDA-cleared test confirming CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM). For reauth: must have documentation from prescriber indicating improvement in condition and that member is being monitored for neurological side effects of Cerdelga.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration	365 days
Other Criteria	Not Applicable

CHEMET

Products Affected

- Chemet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have blood lead level greater than 45 micrograms per deciliter. Must have chart documentation of identification and removal of the cause of lead exposure. For reauth: must meet initial authorization criteria and have clinical rationale from the prescriber for continuation of treatment.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Toxicologist or other clinician who has experience with chelating agents
Coverage Duration	30 days
Other Criteria	Not Applicable

CIMZIA POWDER

Products Affected

- Cimzia Powder for Reconst

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with certolizumab pegol.
Required Medical Information	Diagnosis. Negative tuberculosis skin test prior to treatment with certolizumab pegol. For RA: must have moderately to severely active RA and must have adequate trial of methotrexate with inadequate response OR must have adequate trial of leflunomide, hydroxychloroquine, or sulfasalazine with an inadequate response or significant side effect/toxicity or must have a contraindication to these therapies if an adequate trial of methotrexate is not possible (e.g. due to significant side effects/toxicities or a contraindication to methotrexate). For ankylosing spondylitis: must have active disease and must have adequate trial of 2 NSAIDs with inadequate response, significant side effects/toxicity or have a contraindication to these therapies. For psoriatic arthritis (peripheral disease): must have active disease AND must have adequate trial of 1 NSAID at target anti-inflammatory dose and of 1 conventional systemic therapy (e.g. methotrexate, cyclosporine, leflunomide, sulfasalazine) with inadeq responses, significant side effects/toxicities unless contraindicated. For psoriatic arthritis (axial, skin, nail, enthesitis, or dactylitis dominant): must have active disease and an adequate trial of 2 NSAIDs at target anti-inflammatory dose with inadeq response or sig. side effects/toxicities unless contraindicated. For Crohn's: must have moderately to severely active Crohn's, must have adequate trial of 1 conventional therapy including a corticosteroid or an immunosuppressant (e.g. azathioprine, 6-mercaptopurine) with inadequate response or significant side effects/toxicity or have a contraindication. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	RA, ankylosing spondylitis: rheumatologist. Psoriatic arthritis: rheumatologist or dermatologist. Crohn's: gastroenterologist.
Coverage Duration	365 days

PA Criteria	Criteria Details
Other Criteria	Not Applicable

CIMZIA SYRINGE

Products Affected

- Cimzia

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with certolizumab pegol.
Required Medical Information	Diagnosis. Negative tuberculosis skin test prior to treatment with certolizumab pegol. For RA: must have moderately to severely active RA and must have adequate trials of etanercept and adalimumab with inadequate responses. For ankylosing spondylitis, psoriatic arthritis: must have active disease and must have adequate trials of etanercept and adalimumab with inadequate responses. For Crohn's: must have moderately to severely active Crohn's, must have adequate trial of 1 conventional therapy including a corticosteroid or an immunosuppressant (e.g. azathioprine, 6-mercaptopurine) with inadequate response or significant side effects/toxicity or have a contraindication, and must have adequate trial of adalimumab with inadequate response. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	RA, ankylosing spondylitis: rheumatologist. Psoriatic arthritis: rheumatologist or dermatologist. Crohn's: gastroenterologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

CINRYZE

Products Affected

- Cinryze

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of HAE and confirmatory laboratory values on 2 separate instances (copy of laboratory reports required, must include reference ranges). For Type I: low C4 complement level in mg/dL, normal C1q complement component level in mg/dL (C1q complement component level not required for patients under age of 18 or patients whose symptoms began before age 18), and either low C1 esterase inhibitor antigenic level in mg/dL or low C1 esterase inhibitor functional level expressed as a percent. For Type II: low C4 complement level in mg/dL, normal C1q complement component level in mg/dL (C1q complement component level not required for patients under age of 18 or patients whose symptoms began before age 18), and low C1 esterase inhibitor functional level expressed as a percent. For Type III: chart documentation of exclusion of other possible diagnoses and/or causes of angioedema. For all types, must have chart documentation of each previous HAE attack to demonstrate member is candidate for prophylactic therapy to include one of the following: history of frequent HAE attacks (defined as 2 or more HAE attacks per month) or history of severe HAE attacks (defined as 1 or more abdominal attack in past 12 months or any attack of respiratory tract which compromised airway). Must have had trial and failure of, intolerance to, or contraindication to an attenuated androgen (e.g. danazol, stanozolol, oxandrolone). For reauth, must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 9 years or older
Prescriber Restrictions	By or under the direction of a HAE specialist (defined as an allergist/immunologist who attests to clinical experience in HAE).
Coverage Duration	Initial: 120 days. Reauth: 365 days.
Other Criteria	Must be used as prophylactic therapy for prevention of HAE attacks. If clinical documentation confirms the required criteria, C1 inhibitor [human] will be approved after consultation with a Medical Director.

CLONIDINE ER

Products Affected

- clonidine HCl oral tablet extended release 12 hr

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of Attention Deficit Hyperactivity Disorder. Must have adequate trial and failure of clonidine with inadequate response or significant side effects/toxicity unless contraindicated. Must have adequate trial of a CNS stimulant (e.g. methylphenidate, amphetamine salts) with inadequate response or significant side effects/toxicity unless contraindicated.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

COMETRIQ

Products Affected

- Cometriq oral capsule 100 mg/day(80 mg x1-20 mg x1), 140 mg/day(80 mg x1-20 mg x3), 60 mg/day (20 mg x 3/day)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

CORLANOR

Products Affected

- Corlanor

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Blood pressure less than 90/50mmHg. Current acute decompensated heart failure. Sick sinus syndrome, sinoatrial block, or 3rd degree AV block, unless a functioning demand pacemaker is present. Severe hepatic impairment. Dependence on a pacemaker, where heart rate is maintained exclusively by the pacemaker, such as ventricular or atrioventricular pacing more than 40% of the day or demand pacemakers set to a rate greater than 60 beats per minute.
Required Medical Information	Diagnosis. Must currently be taking a beta-blocker (e.g., metoprolol succinate sustained-release, carvedilol, bisoprolol) at maximum tolerated dose for heart failure unless a prior trial with beta-blocker therapy resulted in significant side effect/toxicity or there is a contraindication to use of beta-blocker therapy (e.g., bronchospastic disease such as chronic obstructive pulmonary disease and asthma, severe hypotension or bradycardia).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Cardiologist
Coverage Duration	365 days
Other Criteria	Not Applicable

COSENTYX

Products Affected

- Cosentyx
- Cosentyx Pen

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with secukinumab.
Required Medical Information	Diagnosis. Negative TB skin test. Must be up to date with all immunizations according to current immunization guidelines prior to starting treatment with secukinumab. Must have adequate trials of etanercept and adalimumab with inadequate responses or significant side effects/toxicity unless contraindicated. For plaque psoriasis: Must have moderate to severe plaque psoriasis, must have minimum body surface area of at least 5% (not required if on palms, soles, head/neck, or genitalia). For psoriatic arthritis and ankylosing spondylitis: must have active disease. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Ankylosing spondylitis: rheumatologist. Psoriatic arthritis: rheumatologist, dermatologist. Plaque psoriasis: dermatologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

COTELLIC

Products Affected

- Cotellic

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming BRAFV600E or BRAFV600K mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

CYSTAGON

Products Affected

- Cystagon

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of a clinical work-up to rule out other diagnoses and clinical rationale for the diagnosis and exclusion of other diagnoses. Diagnosis must be confirmed by having all of the following: elevated white blood cell cystine levels greater than 2nmol per 1/2 cystine per mg of protein, laboratory result confirming CTNS gene mutation, and clinical symptoms of nephropathic cystinosis including electrolyte imbalances and polyuria. For reauth: must have documentation from prescriber indicating improvement in condition and a reduction in WBC cystine levels since starting treatment with oral cysteamine.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a nephrologist or physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

CYSTARAN

Products Affected

- Cystaran

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis (dx). Must have chart documentation of a clinical work-up to rule out other dx and clinical rationale for dx and exclusion of other dx. Must have chart documentation of elevated baseline white blood cell (WBC) cystine level greater than 2nmol per 1/2 cystine per mg of protein, laboratory result confirming CTNS gene mutation, clinical symptoms consistent with dx (i.e. photophobia, corneal erosions, keratophathies), AND ophthalmologic exam confirming dx. For reauth: must have documentation from prescriber indicating improvement in condition and indicating evaluation of compliance with therapy.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with an ophthamologist or a physician who specializes in the treatment of inherited metabolic disorders.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

DALIRESP

Products Affected

- Daliresp

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Moderate to severe liver impairment.
Required Medical Information	Diagnosis of GOLD Stage III or IV COPD associated with chronic bronchitis. Documentation of COPD exacerbation within the past year. Must have adequate trial and failure of inhaled long-acting beta-agonist or inhaled long-acting anticholinergic or a contraindication to these agents. Must have trial and failure of inhaled glucocorticosteroid or a contraindication to these agents. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

DEPEN

Products Affected

- Depen Titratabs

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have baseline (within 6 months) urinalysis, complete blood cell count, platelet count, and hemoglobin. For Wilson's disease, must have chart documentation of how diagnosis was confirmed including at least one of the following: hepatic parenchymal copper content greater than or equal to 250 micrograms per gram dry weight, presence of Kayser-Fleischer Ring in cornea, serum ceruloplasmin level less than 50mg/L, basal 24-hour urinary excretion of copper greater than 100 micrograms (1.6 millimoles), or genetic testing indicating mutation in ATP7B gene. For Cystinuria: must have chart documentation of how diagnosis was confirmed. For Rheumatoid Arthritis: must have severely active disease, must have an adequate trial of methotrexate with inadequate response or significant side effects or toxicity or have a contraindication, and must have an adequate trial of leflunomide, hydroxychloroquine, minocycline, or sulfasalazine with inadequate response or significant side effects or toxicity or have a contraindication. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Wilson's disease, cystinuria: by or in consultation with physician who specializes in the treatment of inherited metabolic disorders. RA: rheumatologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

DRONABINOL

Products Affected

- dronabinol

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For chemotherapy induced nausea and vomiting, patient must be receiving chemotherapy. For AIDS anorexia, patient must have diagnosis of AIDS with anorexia and weight loss. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist, gastroenterologist, or infectious disease physician
Coverage Duration	180 days
Other Criteria	B vs. D determination will be made prior to clinical criteria being applied.

DUAVEE

Products Affected

- Duavee

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Undiagnosed abnormal uterine bleeding. Known, suspected, or past history of breast cancer. Known or suspected estrogen-dependent neoplasia. Active or past history of venous thromboembolism and/or arterial thromboembolism. Known hepatic impairment or disease. Known protein C, protein S, or antithrombin deficiency or other known thrombophilic disorders. Pregnancy, women who may become pregnant, and nursing mothers.
Required Medical Information	Diagnosis. For moderate to severe vasomotor symptoms associated with menopause: must have documentation of clinical rationale for continued use of Duavee (including an explanation of the member's specific benefit of the drug and how that benefit outweighs the potential risk), documentation demonstrating return of significant vasomotor symptoms when withdrawal of estrogen therapy is tried, AND documentation of previous adequate trial of Femring with an inadequate response or significant side effect/toxicity. For osteoporosis prophylaxis: must have adequate trials with a bisphosphonate (e.g. alendronate) and raloxifene with inadequate responses or significant side effects/toxicities unless contraindicated. For vasomotor symptom reauth: must have documentation of clinical rationale for continued use of Duavee (including an explanation of the member's specific benefit of the drug and how that benefit outweighs the potential risk) and documentation demonstrating trial of Duavee withdrawal with return of significant vasomotor symptoms. For osteoporosis reauth: must have documentation indicating continued benefit with use of Duavee.
Age Restrictions	Age 65 years or older: criteria apply. Age less than 65 years: criteria do not apply.
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

DUOPA

Products Affected

- Duopa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Must have a diagnosis of advanced Parkinson's disease including the following: a clear motor response to levodopa in the trial below, chart documentation of the Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale, and chart documentation of motor fluctuations including either or both: initial benefit after dose of levodopa in the trial below followed by return of parkinsonian features before onset of benefit from subsequent dose (e.g. wearing off) and/or evidence of involuntary movements when therapeutic effect of levodopa in the trial below is maximal (e.g. peak dose dyskinesia). Must have an adequate trial of concomitant therapy with carbidopa/levodopa and a dopamine agonist (e.g. pramipexole) with an inadequate response, despite modification in levodopa dosage, or significant side effects/toxicity or have a contraindication to a therapy. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Neurologist
Coverage Duration	365 days
Other Criteria	B vs. D determination will be made prior to clinical criteria being applied.

DYSPORT

Products Affected

- Dysport

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

EGRIFTA

Products Affected

- Egrifta subcutaneous recon soln 1 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Active malignancy, history of malignancy, pregnant female, or disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation, or head trauma
Required Medical Information	Diagnosis of lipodystrophy with excess abdominal fat and underlying diagnosis of HIV infection. Must be stable on an antiretroviral regimen for at least 8 weeks prior to beginning tesamorelin. Must have waist circumference of at least 95cm (37.4in) and a waist to hip ratio of at least 0.94 for males OR waist circumference of at least 94cm (37in) and a waist to hip ratio of at least 0.88 for females. Must have baseline (within past 6 months) evaluation of fasting blood glucose and IGF-1. Must have baseline negative pregnancy test prior to initiation of therapy if member is a woman of childbearing potential. For reauth: must have documentation showing decreases from baseline in both waist circumference and waist to hip ratio, no active malignancy or history of malignancy, and showing fasting blood glucose and IGF-1 levels are being monitored.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with an endocrinologist or physician who specializes in the treatment of HIV/AIDS
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

ELAPRASE

Products Affected

- Elaprase

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Confirmed diagnosis of Hunter Syndrome (mucopolysaccharidosis type II).
Age Restrictions	Age 16 months or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

ELIDEL AND TOPICAL TACROLIMUS

Products Affected

- Elidel
- tacrolimus topical

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Weakened or compromised immune system
Required Medical Information	Diagnosis. For topical tacrolimus: must have adequate trial and failure of moderate to high potency topical corticosteroid or have a contraindication to this therapy (such as dermatitis on face, genitalia). For pimecrolimus (Elidel): must have adequate trial and failure of moderate to high potency topical corticosteroid or have a contraindication to this therapy (such as dermatitis on face, genitalia) AND must have adequate trial and failure of topical tacrolimus with inadequate response or significant side effect/toxicity or have a contraindication to this therapy. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Elidel, tacrolimus 0.03%: age 2 years or older. Tacrolimus 0.1%: age 16 years or older.
Prescriber Restrictions	No Prescriber Restrictions.
Coverage Duration	365 days
Other Criteria	Not Applicable

EMCYT

Products Affected

- Emcyt

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

EMFLAZA

Products Affected

- Emflaza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Chart documentation of baseline motor function, strength (e.g., Brooke upper extremity functional score, Modified Medical Research Council score for manual muscle testing, North Star Ambulatory Assessment/Timed Functional Test). Must have previous trial and failure of prednisone unless intolerant or contraindicated. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

ENBREL

Products Affected

- Enbrel subcutaneous recon soln
- Enbrel subcutaneous syringe
- Enbrel SureClick

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with etanercept.
Required Medical Information	Diagnosis. Negative tuberculosis skin test. For RA and JIA: must have diagnosis of moderately to severely active disease, must have adequate trial of methotrexate with inadequate response (if significant side effects/toxicity or contraindication to methotrexate must have adequate trial of hydroxychloroquine, leflunomide, or sulfasalazine for RA and of leflunomide or sulfasalazine for JIA). For psoriatic arthritis (peripheral disease): must have moderately to severely active psoriatic arthritis AND must have adequate trial of 1 NSAID at target anti-inflammatory dose and of 1 conventional systemic therapy (e.g. methotrexate, cyclosporine, leflunomide, sulfasalazine) with inadequate responses or significant side effects/toxicities or have contraindication to these therapies. For psoriatic arthritis (axial, skin, nail, enthesitis, or dactylitis dominant): must have an adequate trial of 2 NSAIDs at target anti-inflammatory dose with inadeq response or sig. side effects/toxicities unless contraindicated. For ankylosing spondylitis: must have active disease and must have adequate trial of 2 NSAID at target anti-inflammatory dose with inadequate response or significant side effects/toxicity or have a contraindication. For plaque psoriasis: must have chronic moderate to severe plaque psoriasis, must have minimum BSA involvement of at least 5% (not required if plaque psoriasis on palms, soles, head/neck, or genitalia), must have adequate trial of 1 topical treatment or phototherapy or photochemotherapy with inadequate response or significant side effects/toxicity or have a contraindication, and must have adequate trial of 1 conventional systemic therapy (e.g. methotrexate, acitretin, cyclosporine) with inadequate response or significant side effects/toxicity or have a contrainidication. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	RA, JIA, ankylosing spondylitis: rheumatologist. Psoriatic arthritis: rheumatologist or dermatologist. Plaque psoriasis: dermatologist.

PA Criteria	Criteria Details
Coverage Duration	365 days
Other Criteria	Not Applicable

ENTECAVIR

Products Affected

- Baraclude oral solution
- entecavir

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have documentation of results of Hep B Virus Drug Resistance panel if previously received antiviral tx regimen for Hep B. Must have documentation of baseline eval and results for following tests: Hep B virus (HBV) DNA viral load, hepatitis B e antigen (HBeAg), antibody to hepatitis B e antigen (anti-HBe), hepatitis B surface antigen (HBsAg), antibody to hepatitis surface antigen (anti-HBs), liver biopsy (if available), alanine aminotransferase (ALT) level and assay reference range. For reauth: must have doc from prescriber indicating continued benefit from tx, chart doc that mbr is compliant w/ tx, doc of recent HBV DNA level, chart doc of HBV Drug Resistance panel if mbr has evidence or virologic breakthrough (greater than 10-fold increase in serum HBV DNA from nadir during tx in mbr who had initial virologic response) while compliant w/ tx, and doc of of HBeAg/Anti-HBe/HBsAg/Anti-HBs (for mbrs with HBeAg positive and for mbrs with HBeAg negative not falling under any other indications).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Infectious disease physician, gastroenterologist, hepatologist, or transplant physician
Coverage Duration	365 days or until disease progression or clearance
Other Criteria	Regimens/requirements based upon AASLD Practice Guidelines for Chronic Hepatitis B. For HBeAg+ chronic HBV: must meet 1 ALT criterion (ALT greater than or equal to 2xULN OR evidence of moderate/severe inflammation or signif. fibrosis on biopsy) and have HBV DNA level greater than 20,000 IU/mL (not required for pediatric patients if ALT greater than or equal to 2xULN for longer than 6 months). For HBeAg- chronic HBV: must meet 1 ALT criterion (ALT greater than or equal to 2xULN, ALT greater than 1xULN w/ evidence of moderate/severe inflammation or signif. fibrosis on biopsy, ALT less than

PA Criteria	Criteria Details
	or equal to ULN w/ ALT increased over time) and 1 HBV DNA criterion (HBV DNA greater than 20,000 IU/mL, HBV DNA greater than 2,000 IU/mL w/ evidence of moderate/severe inflammation or signif. fibrosis on biopsy, HBV DNA less than or equal to 2,000 IU/mL w/ HBV DNA increased over time). For cirrhosis w/ HBV: must have HBV DNA greater than 2,000 IU/mL OR detectable HBV DNA level w/ elevated ALT. For HBV mbr who had liver txfr for HBV or who received solid organ txfr from HBV+ donor: approve regardless of HBV DNA and ALT levels. For HBV carrier who needs immunosuppressive or cytotoxic tx: must be HBsAg+, have planned course of cancer chemotx or immunosuppressive tx. Reauth for HBeAg+: approve x1 year until all of following are met (loss of HBeAg, undetectable serum HBV DNA, completed 6-12 months of additional tx after appearance of anti-HBe. Reauth for HBeAg-: approve x1 yr until loss of HBsAg. Reauth for cirrhosis, for liver txfr for HBV, or for solid organ txfr from HBV+ donor: long-term tx approvable. Reauth for HBV carriers receiving immunosuppressive or cytotoxic tx: mbr w/ baseline HBV DNA less than 2,000 IU/mL should continue x6 months after completion of chemotx or immunosuppressive tx, mbr w/ baseline HBV DNA greater than 2,000 IU/mL should continue until reach therapeutic endpoints for immunocompetant HBV as listed above.

EPCLUSA

Products Affected

- Epclusa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of chronic Hep C. Doc of prior treatment (tx) for Hep C. Chart doc of lab genotype (GT) result, detectable baseline HCV RNA level (incl. assay date, ref. range), test indicating presence or absence of cirrhosis (e.g. F4 score on liver biopsy from within past 3 years, MRI, ultrasound, CT scan). For GT 1, 4, 5, 6: must have clinical rationale describing why Harvoni cannot be used.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Infectious disease physician, gastroenterologist, hepatologist, HIV specialist, or transplant physician
Coverage Duration	12 or 24 weeks based on GT, prior tx, presence of cirrhosis
Other Criteria	Regimens/requirements based on AASLD/IDSA Hep C Tx Guidelines. Interferon (IFN), protease inhibitor (PI), ribavirin (RBV), simeprevir (SIM), sofosbuvir (SOF). GT 1, tx naive, unable to use Harvoni: approve x12 wks. GT 1 treatment-experienced w/ IFN/RBV or w/ NS3 PI/IFN/RBV, unable to use Harvoni: approve x12 wks. GT 2, tx naive: approve x12 wks. GT 2, treatment-experienced w/ IFN/RBV: approve x12 wks. GT 2, treatment-experienced w/ SOF/RBV: +RBV approve x12 wks. GT 3, tx naive: approve x12 wks. GT 3, treatment-experienced w/ IFN/RBV, non-cirrhotic: approve x12 wks. GT 3, treatment-experienced w/ IFN/RBV, cirrhotic: + RBV approve x12 wks. GT 3, treatment experienced w/ SOF/RBV: +RBV approve x12 wks. GT 4, 5, 6 AND unable to use Harvoni: approve x12 wks. Decompensated cirrhosis, GT 1 and 4, SOF naive, unable to use Harvoni: +RBV approve x12 wks OR -RBV (if contraindicated) approve x24 wks. Decompensated cirrhosis, GT 1 and 4, treatment-experienced w/ SOF, unable to use Harvoni: +RBV approve x24 weeks. Decompensated cirrhosis, GT 2 and 3: +RBV approve x12 wks.

EPIVIR HBV

Products Affected

- Epivir HBV oral solution
- lamivudine oral tablet 100 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Hepatitis B Virus Drug Resistance panel showing resistance to prior tx w/ lamivudine HBV
Required Medical Information	Diagnosis. Must have documentation of results of Hep B Virus Drug Resistance panel if previously received antiviral tx regimen for Hep B. Must have documentation of baseline eval and results for following tests: Hep B virus (HBV) DNA viral load, hepatitis B e antigen (HBeAg), antibody to hepatitis B e antigen (anti-HBe), hepatitis B surface antigen (HBsAg), antibody to hepatitis surface antigen (anti-HBs), liver biopsy (if available), alanine aminotransferase (ALT) level and assay reference range. Must have an adequate trial of Baraclude with inadequate response, significant side effect/toxicity, contraindication, or documented viral resistance to Baraclude or have clinical rationale to support use of Epivir HBV over Baraclude. For reauth: must have doc from prescriber indicating continued benefit from tx, chart doc that mbr is compliant w/ tx, doc of recent HBV DNA level, chart doc of HBV Drug Resistance panel if mbr has evidence of virologic breakthrough (greater than 10-fold increase in serum HBV DNA from nadir during tx in mbr who had initial virologic response) while compliant w/ tx, and doc of HBeAg/Anti-HBe/HBsAg/Anti-HBs (for mbrs with HBeAg positive and for mbrs with HBeAg negative not falling under any other indications).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Infectious disease physician, gastroenterologist, hepatologist, or transplant physician
Coverage Duration	365 days or until disease progression or clearance
Other Criteria	Regimens/requirements based upon AASLD Practice Guidelines for Chronic Hepatitis B. For HBeAg+ chronic HBV: must meet 1 ALT criterion (ALT greater than or equal to 2xULN OR evidence of moderate/severe inflammation or signif. fibrosis on biopsy) and have HBV DNA level greater than 20,000 IU/mL (not required for pediatric patients if ALT greater than or equal to 2xULN for longer than 6 months).

PA Criteria	Criteria Details
	For HBeAg- chronic HBV: must meet 1 ALT criterion (ALT greater than or equal to 2xULN, ALT greater than 1xULN w/ evidence of moderate/severe inflammation or signif. fibrosis on biopsy, ALT less than or equal to ULN w/ ALT increased over time) and 1 HBV DNA criterion (HBV DNA greater than 20,000 IU/mL, HBV DNA greater than 2,000 IU/mL w/ evidence of moderate/severe inflammation or signif. fibrosis on biopsy, HBV DNA less than or equal to 2,000 IU/mL w/ HBV DNA increased over time). For cirrhosis w/ HBV: must have HBV DNA greater than 2,000 IU/mL OR detectable HBV DNA level w/ elevated ALT. For HBV mbr who had liver txfr for HBV or who received solid organ txfr from HBV+ donor: approve regardless of HBV DNA and ALT levels. For HBV carrier who needs immunosuppressive or cytotoxic tx: must be HBsAg+, have planned course of cancer chemotx or immunosuppressive tx. Reauth for HBeAg+: approve x1 year until all of following are met (loss of HBeAg, undetectable serum HBV DNA, completed 6-12 months of additional tx after appearance of anti-HBe. Reauth for HBeAg-: approve x1 yr until loss of HBsAg. Reauth for cirrhosis, for liver txfr for HBV, or for solid organ txfr from HBV+ donor: long-term tx approvable. Reauth for HBV carriers receiving immunosuppressive or cytotoxic tx: mbr w/ baseline HBV DNA less than 2,000 IU/mL should continue x6 months after completion of chemotx or immunosuppressive tx, mbr w/ baseline HBV DNA greater than 2,000 IU/mL should continue until reach therapeutic endpoints for immunocompetant HBV as listed above.

EPOGEN AND PROCRIT

Products Affected

- Epogen injection solution 2,000 unit/mL, 20,000 unit/2 mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL
- Procrit injection solution 10,000 unit/mL, 2,000 unit/mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL, 40,000 unit/mL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Uncontrolled hypertension, known hypersensitivity to active substance or any excipients of product.
Required Medical Information	Diagnosis. Initial for ribavirin-induced anemia: must have Hgb less than 10g/dL or a 3g/dL decrease from baseline with anemia symptoms and documentation that dose reduction of ribavirin did not resolve anemia. Initial to reduce risk of allogenic blood transfusions: must have Hgb 10-13g/dL and be at high risk for perioperative transfusion due to significant anticipated blood loss and be scheduled to undergo elective, non-cardiac, or nonvascular surgery. Initial for other dx: must have Hgb less than 10g/dL. Initial for anemia due to chemotx for nonmyeloid malignancy: must have documentation of a minimum 2 more months of chemotx planned. Must have iron status evaluated before and during treatment with EPO. Reauth for CKD on dialysis: must have Hgb less than 11g/dL. Reauth for CKD not on dialysis: must have Hgb less than 10g/dL. Reauth for pediatric CKD: must have Hgb less than 12 g/dL. Reauth for anemia due to chemotx for nonmyeloid malignancy: must have Hgb less than 10g/dL and documentation of a minimum 2 more months of chemotx planned. Reauth for other dx: must have Hgb less than 12g/dL.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a nephrologist, hematologist/oncologist, gastroenterologist, hepatologist, transplant physician, surgeon, or an infectious disease physician
Coverage Duration	Initial: 90 days. Reauth: 90 days for d/t chemotx, 180 days for other dx.
Other Criteria	Part B versus Part D determination will made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an ESRD-related condition. If the drug is determined not to be ESRD-related, criteria apply.

ERIVEDGE

Products Affected

- Erivedge

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ESBRIET AND OFEV

Products Affected

- Esbriet oral capsule
- Ofev

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have definitive diagnosis of idiopathic pulmonary fibrosis confirmed by either high-resolution computed tomography (HRCT) or surgical lung biopsy. Must have all other diagnoses ruled out (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity). Must submit documentation of baseline liver function testing, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin. For reauth: must have documentation from prescriber indicating that member still is a candidate for treatment and showing that liver function tests (including ALT, AST, and bilirubin) are being monitored regularly.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Pulmonologist
Coverage Duration	Initial: 90 days. Reauth: 180 days.
Other Criteria	Not Applicable

EUCRISA

Products Affected

- Eucrisa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have adequate trial and failure of moderate to high potency topical corticosteroid or have a contraindication to this therapy (such as dermatitis on face, genitalia) AND must have adequate trial and failure of topical tacrolimus with inadequate response or significant side effect/toxicity or have a contraindication to this therapy. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

EXJADE

Products Affected

- Exjade
- Jadenu

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Concomitant advanced malignancy or high-risk myelodysplastic syndrome. Serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance less than 40mL/min.
Required Medical Information	Diagnosis. Must have platelet count greater than or equal to 50,000. For treatment of chronic iron overload due to non-transfusion dependent thalassemia syndromes: must have liver iron concentration of at least 5mg of iron per gram dry weight and serum ferritin greater than 300mcg/L. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Due to transfusions: age 2 years or older. Not due to transfusions: age 10 years or older.
Prescriber Restrictions	Hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

FABRAZYME

Products Affected

- Fabrazyme intravenous recon soln 35 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For males: must have diagnosis of Fabry disease based upon clinical symptoms or by genetic testing. For females: must have presumed symptoms of Fabry disease (heterozygous carriers) based on family history and/or genetic testing. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

FANAPT

Products Affected

- Fanapt oral tablet 1 mg, 10 mg, 12 mg, 2 mg, 4 mg, 6 mg, 8 mg
- Fanapt oral tablets,dose pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have adequate trial and failure of risperidone and 1 other atypical antipsychotic (including, but not limited to: aripiprazole, olanzapine, quetiapine, ziprasidone) with inadequate responses or intolerance.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

FARESTON

Products Affected

- Fareston

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have previous inadequate response or intolerance to tamoxifen.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

FARYDAK

Products Affected

- Farydak oral capsule 10 mg, 15 mg, 20 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

FENTANYL CITRATE

Products Affected

- Abstral sublingual tablet 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg
- fentanyl citrate buccal lozenge on a handle 1,200 mcg, 1,600 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg
- Fentora buccal tablet, effervescent 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg
- Lazanda nasal spray,non-aerosol 100 mcg/spray, 300 mcg/spray, 400 mcg/spray
- Subsys sublingual spray,non-aerosol 100 mcg/spray, 200 mcg/spray, 400 mcg/spray, 600 mcg/spray, 800 mcg/spray

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Treatment of acute or postoperative pain.
Required Medical Information	Diagnosis. Must be opioid tolerant, defined as requiring medication for a week or longer containing at least 60mg/day of morphine. Must currently be using a long-acting opioid. Brand fentanyl products only covered if documentation is submitted indicating past failure or intolerance to generic oral transmucosal fentanyl. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or pain specialist
Coverage Duration	365 days
Other Criteria	Not Applicable

FERRIPROX

Products Affected

- Ferriprox

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Must have transfusional iron overload due to thalassemia syndromes. Must have adequate trial of iron chelator such as deferoxamine or deferasirox. Must have an assessment of ANC prior to starting deferiprone. For reauth: must have documentation from prescriber indicating improvement in condition and showing that ANC is being monitored on a weekly basis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

FETZIMA

Products Affected

- Fetzima oral capsule,Ext Rel 24hr dose pack
- Fetzima oral capsule,extended release 24 hr 120 mg, 20 mg, 40 mg, 80 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Concomitant therapy with monoamine oxidase inhibitor, linezolid, or intravenous methylene blue.
Required Medical Information	Diagnosis. Must have adequate trial and failure of one generic serotonin norepinephrine reuptake inhibitor (such as venlafaxine ER) indicated for the treatment of major depressive disorder AND one generic selective serotonin reuptake inhibitor (such as citalopram or fluoxetine). If transitioning from a monoamine oxidase inhibitor to levomilnacipran, must have at least a 14-day washout period in between.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

FIRST GENERATION ANTIHISTAMINES

Products Affected

- Arbinoxa oral tablet
- carbinoxamine maleate
- clemastine oral tablet 2.68 mg
- cyproheptadine
- diphenhydramine HCl oral elixir
- hydroxyzine HCl oral solution 10 mg/5 mL
- hydroxyzine HCl oral tablet
- hydroxyzine pamoate
- promethazine oral

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Approve carbinoxamine, clemastine, cyproheptadine, diphenhydramine, hydroxyzine, and promethazine if prior trial and failure of levocetirizine for allergic rhinitis, allergic conditions, or urticaria. Approve promethazine if prior trial and failure of ondansetron for nausea and vomiting. Approve diphenhydramine if prior trial and failure of lorazepam, trazodone, ramelteon, or doxepin 3mg or 6mg (Silenor) for insomnia. Approve hydroxyzine if prior trial and failure of two therapies (such as SSRIs and SNRIs) for anxiety. For all other FDA-approved indications, no prior drug trials are required. For reauth (any indication): must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 65 years or older: criteria apply. Age less than 65 years: criteria do not apply.
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

FYCOMPA

Products Affected

- Fycompa oral suspension
- Fycompa oral tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have had an inadequate response or intolerance to 2 other antiepileptic drugs (such as carbamazepine, oxcarbazepine, or phenytoin) and be using perampanel as adjunctive therapy to other antiepileptic drugs (which can include medication from trial above). Must have documentation indicating the member will be monitored for the psychiatric side effects of the perampanel. For reauth: must have documentation from prescriber indicating improvement in condition and monitoring for psychiatric side effects.
Age Restrictions	Age 12 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	365 days
Other Criteria	Not Applicable

GAMASTAN

Products Affected

- GamaSTAN S/D

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	1 month
Other Criteria	Not Applicable

GARDASIL

Products Affected

- Gardasil (PF)
- Gardasil 9 (PF)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	None
Age Restrictions	Between the ages of 9 and 26 years
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	3 doses per 365 days
Other Criteria	Not Applicable

GATTEX

Products Affected

- Gattex One-Vial

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Active intestinal obstruction or active malignancy.
Required Medical Information	Diagnosis of short bowel syndrome defined as less than 200cm of residual functional small intestine. Must provide date of bowel resection, baseline parenteral or intravenous nutrition (PN/IV) support schedule including frequency and volume, colonoscopy within 6 months before starting teduglutide (if appropriate), and baseline (within 6 months) lab monitoring of bilirubin, alkaline phosphatase, lipase, and amylase. Must be receiving parenteral or intravenous nutrition support at least 3 times per week. For reauth: must have documentation from prescriber indicating improvement in condition, that member has weaned off or decreased PN/IV requirements, that the member had a colonoscopy (if appropriate) after 1 year of teduglutide treatment and at least every 5 years after the 1st year, and that member is undergoing laboratory testing of bilirubin, alkaline phosphatase, lipase, and amylase every 6 months.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with a gastroenterologist
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

GAUCHER DISEASE AGENTS

Products Affected

- Cerezyme intravenous recon soln 400 unit
- Elelyso
- VPRIV

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of Gaucher disease with any of the following: anemia (defined as hemoglobin less than 12g/dL in males or less than 11g/dL in females for members older than 12 years of age, hemoglobin less than 10.5g/dL for members between 2 to 12 years of age, hemoglobin less than 9.5g/dL for members between 6 months to 2 years of age, or hemoglobin less than 10.1g/dL for members less than 6 months of age), thrombocytopenia (defined as platelet count less than 100,000), hepatomegaly (defined as liver size greater than or equal to 1.25 times normal), splenomegaly (defined as spleen size greater than 0.2% of body weight), or bone disease (defined as having one of the following: avascular necrosis, erlenmeyer flask deformity, lytic disease, marrow infiltrations, osteopenia, osteosclerosis, pathological fracture, or radiological evidence of joint deterioration). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a hematologist, a physician who specializes in the treatment of inherited metabolic disorders, or a center that specializes in the treatment of Gaucher disease.
Coverage Duration	365 days
Other Criteria	Not Applicable

GILENYA

Products Affected

- Gilenya

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. On concomitant therapy with antineoplastic, immunosuppressive, or immune-modulating therapies. Experienced any of the following in the past 6 months: myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III or IV heart failure. Presence of Mobitz Type II second-degree or third degree antrioventricular block or sick sinus syndrome, unless also has functioning pacemaker. Currently treated with Class Ia or Class III anti-arrhythmic medication.
Required Medical Information	Diagnosis of relapsing form of multiple sclerosis. Must have recent (within 6 months) CBC and transaminase and bilirubin levels. Must have documentation that member will be observed for 6 hours following initial dose of fingolimod for signs/symptoms of bradycardia. Must demonstrate immunity to varicella zoster virus by VZV antibody serology or must submit chart documentation VZV vaccination, including date. Must have previous adequate trial of or intolerance to an interferon product (e.g. Avonex or Plegridy) OR glatiramer, OR dimethyl fumarate. Must have baseline ophthalmic evaluation of macula (all patients) and spirometric evaluation of respiratory function and evaluation of diffusion lung capacity for carbon monoxide (if also have pre-existing lung disease, such as asthma or COPD) . Must have recent ECG and baseline QTc interval of less than or equal to 500ms. For reauth: must have documentation from prescriber indicating improvement/stabiliziation in condition, a follow-up ophthalmic evaluation of macula within 3-4 months of starting fingolimod (required for 1st reauth only), and that CBC and transaminase and bilirubin levels are being monitored consistently.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 120 days. Reauth: 365 days.
Other Criteria	Not Applicable

GILOTRIF

Products Affected

- Gilotrif oral tablet 20 mg, 30 mg, 40 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For first line treatment of metastatic non-small cell lung cancer, must have chart documentation of lab result confirming epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

GLEEVEC

Products Affected

- Gleevec oral tablet 100 mg, 400 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

GLEOSTINE

Products Affected

- Gleostine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

GRALISE

Products Affected

- Gralise 30-Day Starter Pack
- Gralise oral tablet extended release 24 hr 300 mg, 600 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of Postherpetic Neuralgia. Must have adequate trial and failure of tricyclic antidepressant unless contraindicated. Must have adequate trial and failure of gabapentin defined as either failure due to insufficient efficacy at dose of at least 1800mg/day OR chart documented failure due to intolerance despite slow dose titration.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

GRASTEK

Products Affected

- Grastek

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	History of any severe systemic allergic reaction. History of eosinophilic esophagitis. Severe, unstable or uncontrolled asthma. On concomitant immunotherapy.
Required Medical Information	Diagnosis. Must have moderate to severe grass pollen-induced allergic rhinitis with or without conjunctivitis. Must have diagnosis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens (i.e. Sweet Vernal, Orchard, Perennial Rye, Kentucky Blue Grass) and chart documentation demonstrating seasonal symptoms to grass-pollen from the previous pollen season. Must have chart documentation demonstrating daily concomitant use of an inhaled nasal corticosteroid (i.e. fluticasone) and an oral antihistamine (i.e. levocetirizine) during the previous pollen season with inadequate responses or significant side effects/toxicities or have contraindication to these therapies. Must have plan for first dose to be administered in physician office due to potential for life-threatening allergic reactions, including anaphylaxis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 5 years through 65 years
Prescriber Restrictions	Allergist or immunologist
Coverage Duration	180 days
Other Criteria	Therapy must be initiated 12 weeks prior to the onset of grass pollen season. For sustained effectiveness for one grass pollen season after cessation of treatment, may be taken daily for 3 consecutive years (including intervals between grass pollen seasons).

GROWTH HORMONE

Products Affected

- Genotropin
- Genotropin MiniQuick
- Humatrope
- Norditropin FlexPro
- Nutropin AQ Nuspin
- Omnitrope
- Saizen
- Saizen click.easy
- Zomacton

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Active malignancy in the past year. Active proliferative or severe non-proliferative diabetic retinopathy. For Prader-Willi: severely obese (BMI greater than or equal to 97th percentile for age/gender or BMI greater than or equal to 35), history of upper airway obstruction or sleep apnea, or severe respiratory impairment.
Required Medical Information	Diagnosis. Tx plan of dose, monitoring (when seen for f/u, method for determining tx response), anticipated length of use. All dx: chart doc of present height, %, height SD score, pre-tx growth velocity (initial auth), growth velocity on tx (reauth), recent skeletal bone age. Classic growth hormone deficiency (GHD): names/dates of specific GH stim tests, history of irradiation or multiple pituitary hormone deficiency. For chronic renal insufficiency (CRI): estimated date of renal transplant (txfr). Prader-Willi: BMI. For child born small for gestational age (SGA): GA, birth weight and length, height or weight % or SD at birth. Child w/ SHOX deficiency: chart doc of lab of SHOX mutation. Child w/ idiopathic short stature (ISS): doc of how basic ADLs affected, growth rates unlikely to permit attainment of adult height w/i target range based on parental heights. Adults: doc of GHD during childhood and cause of GHD (if applicable), serum IGF-I level while not on GH (if applicable), names and dates of specific GH stim tests (if applicable), whether there is pituitary adenoma (and if so, if tumor size has remained stable x1 yr), doc of possible cause of GH deficiency (severe GH deficiency as child d/t genetic cause, severe GH and receipt of high-dose cranial radiation tx, structural hypothalamic-pituitary disease, CNS tumor, deficiencies in pituitary hormones such as ACTH/TSH/prolactin/gonadotropins/arginine vasopressin). GH stim tests accepted for adults: insulin tolerance test (ITT) required unless contraind (pts w/ known or at high risk for CAD, hx of seizures, severe panhypotituitarism/hypoadrenalism) w/ neg response of peak GH less than or equal to 5ug/L, if ITT contraind glucagon test req unless contraind (malnourished or have not eaten in 48 hrs, pheochromocytoma, insulinoma, severe hypocortisolemia) w/ neg response of peak GH less than or equal to 3ug/L, if ITT and glucagon

PA Criteria	Criteria Details
	contraind arginine test req w/ neg response of peak GH less than or equal to 0.4ug/L.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Endocrinologist, pediatric endocrinologist, or pediatric nephrologist dependent upon diagnosis.
Coverage Duration	Idiopathic short stature: 180 days. Other dx: 365 days.
Other Criteria	Child w/ Classic GHD: must have doc of failure to respond to 2 GH provocative tests (1 test if h/o irradiation or multiple pituitary hormone deficiency) w/ serum peak GH level less than 10ng/mL on stim tests (insulin, levodopa, arginine, clonidine, glucagon), must have at least 2 of following (present height less than 3rd % or greater than 2 SD below mean for gender/age, pre-tx growth velocity less than 7cm/yr for child less than 3 yrs OR less than 4cm for child 3 yrs and older OR less than 10th % for gender/age based on at least 6 months of growth data for child of any age, comparison of skeletal/bone age by x-ray of left hand and wrist greater than 2 SD below chronological age). Growth retardation d/t CRI, Prader-Willi Syndrome, SHOX Deficiency: documented dx of CRI up to time of renal txfr (CRI only), must have at least 1 of following (present height less than 3rd % or greater than 2 SD below mean for gender/age, pre-tx growth velocity less than 7cm/yr for child less than 3 yrs OR less than 4cm for child 3 yrs and older OR less than 10th % for gender/age based on at least 6 months of growth data for child of any age). Turner's Syndrome (females), Noonan Syndrome (males, females), must have 1 of following: present height less than 5th % or greater than 2 SD below mean for gender/age, pre-tx growth velocity less than 7cm/yr for child less than 3 yrs OR less than 4cm for child 3 yrs and older OR less than 10th % for gender/age based on at least 6 months of growth data for child of any age. ISS: must have height SD score of less than -2.25cm/yr. SGA: must have low birth weight (either birth weight less than 2500g at GA of more than 37 wks OR birth weight and length less than 3rd % or less than -2 SD for GA), must have failed to achieve catch-up growth by ages 2-4 with baseline pre-tx height SD score less than -2.5 SD for age/gender. Adult w/ GHD, childhood onset: must stop GH tx x1 mon after completion of linear growth and have GH levels reassessed (not req if high likelihood of GHD defined as IGF-1 less than 84ug/L while off GH tx AND at least 1 of following: severe GHD as child d/t genetic cause, structural hypothalamic-pituitary disease, CNS tumors, severe GHD and receipt of high-dose cranial radiation tx, deficiencies in at least 3 pituitary hormones), must have GHD reassessed w/ 1 GH stim test if

PA Criteria	Criteria Details
	IGF-1 less than 84ug/L while not on GH tx and w/ 2 GH stim tests if IGF-1 normal while not on GH tx. Adult w/ GHD, adult onset: if panhypopituitarism GH stim test not required if pt has deficiencies in at least 3 pituitary hormones and IGF-1 less than 84ug/L while not on GH tx, if no panhypopituitarism w/ low IGF-1 must have GH deficieny confirmed by 2 GH stim tests. For child reauth: d/c if growth velocity on GH tx less than 2.5cm/yr, reached adult height, growth plates fused, need for renal txfr (for CRI), bone age of 14 in females and 16 in males. For any age: must have doc from prescriber indicating improvement in condition.

HARVONI

Products Affected

- Harvoni

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D and chronic Hepatitis C genotypes 4, 5, and 6
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of chronic Hep C. Doc of prior treatment (tx) for Hep C. Chart doc of lab genotype (GT) result, detectable baseline HCV RNA level (incl. assay date, ref. range), test indicating presence or absence of cirrhosis (e.g. F4 score on liver biopsy from within past 3 years, MRI, ultrasound, CT scan).
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Infectious disease physician, gastroenterologist, hepatologist, HIV specialist, or transplant physician
Coverage Duration	12 or 24 weeks based on GT, prior tx, presence of cirrhosis
Other Criteria	Regimens/requirements based on AASLD/IDSA Hep C Tx Guidelines. Interferon (IFN), protease inhibitor (PI), ribavirin (RBV), simeprevir (SIM), sofosbuvir (SOF). GT 1, tx naive, cirrhotic or non-cirrhotic: approve x12 wks. GT 1, treatment-experienced w/ IFN/RBV or PI/IFN/RBV, non-cirrhotic: (+RBV if SIM used in past) approve x12 wks. GT 1, treatment experienced w/ SOF (including SOF/SIM), noncirrhotic: +RBV approve x12 wks. GT 1, treatment-experienced w/ IFN/RBV or PI/IFN/RBV, cirrhotic: +RBV approve x12 weeks OR -RBV (if contraindicated) approve x24 wks OR +RBV approve x24 weeks. GT 1, treatment experienced w/ SOF (including SOF/SIM), cirrhotic: +RBV approve x24 weeks. GT 4: + RBV approve x 12 wks or -RBV (if contraindicated) approve x 24 weeks. GT 5 or 6: approve x12 weeks. Hep C w/ HIV co-infection: regimen based on GT. Hep C post liver txfr in GT 1 or 4: +RBV approve x12 wks OR -RBV (if contraindicated) approve x24 wks. Decompensated cirrhosis, GT 1 and 4, SOF naive: +RBV approve x12 wks OR -RBV (if contraindicated) approve x24 wks. Decompensated cirrhosis, GT 1 and 4, treatment-experienced w/ SOF: +RBV approve x24 weeks.

HETLIOZ

Products Affected

- Hetlioz

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must submit chart documentation describing how diagnosis was confirmed (e.g. sleep-wake logs, melatonin secretion abnormalities, or progress notes, etc.). Patient must be totally blind with no perception of light. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By a neurologist or physician who specializes in sleep medicine
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

HORIZANT

Products Affected

- Horizant

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For RLS: must have adequate trial and failure of pramipexole or ropinerole (defined as insufficient efficacy of pramipexole 0.5mg per day or ropinirole 4mg per day or intolerance to these meds) AND must have adequate trial and failure of gabapentin (defined as insufficient efficacy of gabapentin 1800mg per day or intolerance to med despite slow dose titration or contraindication). For PHN: must have adequate trial and failure of gabapentin (defined as insufficient efficacy of gabapentin 1800mg per day or intolerance to med despite slow dose titration or contraindication) AND must have adequate trial of tricyclic antidepressant unless intolerant or contraindicated.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

HUMAN CHORIONIC GONADOTROPIN

Products Affected

- chorionic gonadotropin, human

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Diagnoses not covered: ovulation induction, obesity.
Required Medical Information	Diagnosis
Age Restrictions	Age 4 years or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

HUMIRA

Products Affected

- Humira Pediatric Crohn's Start
- Humira Pen
- Humira Pen Crohn's-UC-HS Start
- Humira Pen Psoriasis-Uveitis
- Humira subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with adalimumab.
Required Medical Information	Negative TB skin test. For plaque psoriasis (PS):must have chronic mod to severe dx. For ankylosing spondylitis(AS): must have active dx. For all other dx:must have mod to severely active dx. For RA, JIA: adeq trial of methotrexate (MTX) with inadeq response (if sig. side effects/toxicity or contraindication (CI) to MTX must have adequate trial of hydroxychloroquine, leflunomide, or sulfasalazine for RA and of leflunomide or sulfasalazine for JIA). For psoriatic arthritis (peripheral disease): adeq trial of 1 NSAID at target anti-inflammatory dose and 1 conventional systemic tx (e.g. MTX, cyclosporine, leflunomide, sulfasalazine) with inadeq response or sig. side effects/toxicities unless CI. For psoriatic arthritis (axial, skin, nail, enthesitis, or dactylitis dominant): adeq trial of 2 NSAIDs at target anti-inflam dose with inadeq response or sig. side effects/toxicities unless CI. For AS: adeq trial of 2 NSAIDs at target anti-inflam dose with inadeq response or sig. side effects/toxicity or have a CI. For PS: min BSA of at least 5% (not req if on palms, soles, head/neck, genitalia), adeq trial of 1 topical treatment or phototherapy or photochemotherapy with inadeq response or sig. side effects/toxicity unless contraindicated, and adeq trial of 1 conventional systemic therapy (e.g. MTX, acitretin, cyclosporine) with inadeq response or sig. side effects/toxicity unless CI. For Crohns, UC: adeq trial of 1 conventional therapy incl corticosteroid, 5-ASA agent (UC only), or immunosuppressant with inadeq response or sig. side effects/toxicity unless CI. For hidradenitis suppurativa (HS): mod or severe dx (w/ 3 active abscesses, inflammatory nodules, or lesions). For uveitis: adeq trial of 1 immunosuppressant (e.g. MTX, mycophenolate, tacrolimus, cyclosporine) with inadeq response or sig. side effects/toxicity unless CI. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	JIA: age 2 years or older. Crohns: age 6 years or older. Other dx: age 18 years or older.

PA Criteria	Criteria Details
Prescriber Restrictions	RA, JIA, ankylosing spondylitis: rheumatologist. Psoriatic arthritis: rheumatologist, dermatologist. Plaque psoriasis, HS: dermatologist. Crohn's, UC: gastroenterologist. Uveitis: ophthalmologist, rheumatologist.
Coverage Duration	HS initial: 90 days. HS reauth: 365 days. All other dx: 365 days.
Other Criteria	Not Applicable

HYDROXYPROGESTERONE

Products Affected

- hydroxyprogesterone caproate

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Known or suspected carcinoma of the breast, other hormone-sensitive cancer, or history of such conditions. Undiagnosed abnormal vaginal bleeding. Liver dysfunction or disease. Missed abortion. History of hypersensitivity. Current or history of thrombotic or thromboembolic disorders. Use as diagnostic test for pregnancy.
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

IBRANCE

Products Affected

- Ibrance oral capsule 100 mg, 125 mg, 75 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ICLUSIG

Products Affected

- Iclusig oral tablet 15 mg, 45 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Oncologist or Hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ILARIS

Products Affected

- Ilaris (PF) subcutaneous recon soln

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent with canakinumab.
Required Medical Information	Negative TB skin test. For FMF, HIDS, MKD, TRAPS: see Other Criteria. Muckle-Wells (MWS): must have chart doc of diagnosis (dx) confirmed by genetic test (must have doc of lab result confirming mutation in NLRP3 gene) or clinical dx (must have 3 of following: autosomal dominant pattern of disease inheritance, severe fatigue, musculoskeletal symptoms, ocular symptoms, erythematous rash, history of intermittent episodes of fever for at least 24 hours, amyloidosis, hearing loss). Familial Cold Autoinflammatory Syndrome (FCAS): must have chart doc of dx confirmed by genetic test (must have doc of lab result confirming mutation in NLRP3 gene) or a clinical dx (must have 3 of following: recurrent intermittent episodes of fever and rash that primarily follow natural/experimental/both types of generalized cold exposures, autosomal dominant pattern of disease inheritance, age of onset less than 6 months of age, conjunctivitis associated with attacks, absence of deafness/periorbital edema/lymphadenopathy/serositis). SJIA: must have chart doc of dx (must have all of following: history of fever for at least 2 week duration, history of arthritis in 1 or more joints, history of one of following erythematous rash, generalized enlarged lymph nodes, hepatomegaly or splenomegaly, pericarditis/pleuritis/peritonitis), must have active disease (must have 1 of following: erythrocyte sedimentation rate or C-reactive protein level greater than twice upper limit of normal, active fever, active arthritis), must have adequate trial of methotrexate and anakinra with inadequate response or sig side effect/toxicities or contraindication if arthritis currently active OR must have adequate trial of corticosteroid and anakinra with inadequate responses or sig side effects/toxicity or contraindication if arthritis currently not active. Reauth: must have doc from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	MWS, FCAS, FMF, HIDS, MKD, TRAPS: rheumatologist, dermatologist, immunologist, or genetic specialist. SJIA: pediatric rheumatologist.

PA Criteria	Criteria Details
Coverage Duration	Initial: 90 days. Reauth: 90 days (FMF, HIDS, MKD, TRAPS), 365 days (MWS, FCAS, SJIA).
Other Criteria	For Familial Mediterranean Fever (FMF): must have chart doc of dx confirmed by genetic test (must have doc of lab result confirming mutation in MEFV gene) or a clinical dx (must have 3 of following: history of intermittent episodes of fever and pain for 1-3 days duration, autosomal recessive pattern of disease inheritance, presence of peritonitis, presence of arthritis, presence of pleuritis, or presence of erysipelas-like erythema) AND must have adequate trial of colchicine with inadequate response or sig side effects/toxicity unless contraindicated. For Hyperimmunoglobulin D Syndrome (HIDS) and Mevalonate Kinase Deficiency (MKD): must have chart doc of dx confirmed by genetic test (must have doc of lab result confirming mutation in MVK gene) or a clinical dx (must have 3 of following: history of intermittent episodes of fever and inflammation for at least 3 days duration, autosomal recessive pattern of disease inheritance, presence of painful lymph nodes, presence of joint pain, presence of headache, presence of hepatosplenomegaly, presence of skin rash, or presence of abdominal pain, vomiting, diarrhea). For Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS): must have chart doc of dx confirmed by genetic test (must have doc of lab result confirming mutation in TNFRSF1A gene) or a clinical dx (must have 3 of following: history of intermittent episodes of fever for at least 1 week duration, autosomal dominant pattern of disease inheritance, presence of painful lymph nodes, presence of headache, presence of skin rash, presence of muscle cramps, presence of abdominal pain, presence of pleuritis, presence of pericarditis, presence of conjunctivitis or periorbital edema).

IMBRUVICA

Products Affected

- Imbruvica

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

IMMUNE GLOBULINS

Products Affected

- Bivigam
- Carimune NF Nanofiltered intravenous recon soln 6 gram
- Flebogamma DIF intravenous solution 10 %
- Gammagard Liquid
- Gammagard S-D (IgA < 1 mcg/mL)
- Gammaked injection solution 1 gram/10 mL (10 %)
- Gammaplex (with sorbitol)
- Gamunex-C injection solution 1 gram/10 mL (10 %)
- Octagam
- Privigen

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Primary immunodeficiency: IgG less than 500mg/dL (clinical rationale for use required if IgG is 500mg/dL or greater) and history of at least 1 bacterial infection directly attributable to deficiency for initial auth and recent IgG level for reauth. Children w/ ITP: platelet count less than: 20,000 and significant mucous membrane bleeding, 10,000 and minor purpura, or 20,000 and inaccessibility or noncompliance is concern, OR need for any surgery, dental extraction, or other procedure likely to cause blood loss. Adults w/ ITP: plt count less than 30,000 and previous documented inadequate response or intolerance to corticosteroids OR need for surgery likely to cause blood loss (platelet count less than or equal to: 10,000 for dentistry, 30,000 for tooth extraction or regional dental block, 50,000 for minor surgery, 80,000 for major surgery). For pregnant women w/ ITP: plt count less than 100,000, history of splenectomy, or previous delivery of infant(s) w/ autoimmune thrombocytopenia. B-Cell CLL: IgG less than 500mg/dL and previous history of serious bacterial infection requiring antibiotics. CIDP: doc of electrodiagnostic testing confirming dx. Multifocal Motor Neuropathy: must have conduction block and progressive symptomatic disease diagnosed on basis of electrophysiologic findings to r/o other possible conditions. For reauth (all dx): must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Primary immunodeficiency: by or in consultation w/ immunologist, hematologist. ITP: hematologist, oncologist. B-cell CLL: hematologist, oncologist, ID specialist. CIDP, Multifocal Motor Neuropathy: neurologist.

PA Criteria	Criteria Details
Coverage Duration	ITP: 30 days. CIDP, multifocal motor neuropathy: 90 days. Other dx: 365 days.
Other Criteria	BvsD determination will be made prior to clinical criteria being applied.

INCRELEX

Products Affected

- Increlex

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Closed epiphyses, presence of active or suspected neoplasia, allergy to mecasermin, current treatment with growth hormone replacement therapy, secondary forms of IGF-1 deficiency (e.g. growth hormone deficiency, malnutrition not corrected prior to start of mecasermin, hypothyroidism not corrected prior to start of mecasermin, chronic treatment with pharmacological dose of anti-inflammatory steroids)
Required Medical Information	Diagnosis. For growth hormone deletion: must have growth hormone (GH) gene deletion in gene GH1 and developed neutralizing antibodies to GH therapy. For growth failure due to severe IGF-1 deficiency: must have dx of severe IGF-1 deficiency (defined as having all of the following: height standard deviation (SD) score less than or equal to -3.0 for age and sex, basal IGF-1 SD of less than or equal to -3.0 based on lab reference range, normal or elevated GH defined as stimulated serum GH level of greater than 10ng/mL or basal serum GH level greater than 5ng/mL). Must include treatment plan outlining dose, attestation of intent to monitor for side effects and efficacy, and anticipated duration of use. For reauth, must have documentation of recent progress note from prescriber indicating growth and maturation as a result of treatment and that epiphyses have not closed.
Age Restrictions	Age 2 years or older
Prescriber Restrictions	Endocrinologist with appropriate endocrinologist follow-up.
Coverage Duration	365 days
Other Criteria	Not Applicable

INLYTA

Products Affected

- Inlyta oral tablet 1 mg, 5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or Hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

IRESSA

Products Affected

- Iressa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ITRACONAZOLE

Products Affected

- itraconazole

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For dermatalogical mycoses: must be too large to treat with topical antifungals or have not responded to at least 1 topical antifungal agent. For onychomycosis: must be medically significant and non-cosmetic (such as use in diabetic, transplant recipient, or immunocompromised pts) or onychomycosis causing pain that is supported by chart documentation, must have trial and failure of 1 course (3 months) of oral terbinafine. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	90 days
Other Criteria	Not Applicable

JAKAFI

Products Affected

- Jakafi oral tablet 10 mg, 15 mg, 20 mg, 25 mg, 5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection
Required Medical Information	Diagnosis of intermediate or high-risk myelofibrosis includes primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis. Must have a baseline platelet count of at least 50,000 cells/mm3 prior to initiation of ruxolitinib. For diagnosis of polycythemia vera: must currently require phlebotomy and must have adequate trial of hydroxyurea with an inadequate response or significant side effect/toxicity unless contraindicated.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

JUXTAPID

Products Affected

- Juxtapid

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Members who are pregnant, who have moderate or severe hepatic impairment (Child-Pugh category B or C) or active liver disease, or who are on concomitant moderate or strong CYP3A4 inhibitors.
Required Medical Information	Diagnosis of homozygous familial hypercholesterolemia confirmed by genetic testing with functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality or have clinical diagnosis defined as one of the following (1) untreated LDL greater than 500mg/dL AND untreated total cholesterol (TC) greater than 500mg/dL and triglycerides (TG) less than 300mg/dL with both parents with untreated TC greater than 250mg/dL, (2) skin fibroblast LDL receptor activity less than 20% of normal AND untreated TC greater than 500mg/dL and TG less than 300mg/dL with both parents with untreated TC greater than 250mg/dL, (3) presence of cutaneous and tendon xanthomas and corneal arcus in first decade of life AND untreated TC greater than 500mg/dL and TG less than 300mg/dL with both parents with untreated TC greater than 250mg/dL, (4) untreated LDL greater than 500mg/dL AND skin fibroblast LDL receptor activity less than 20% of normal, (5) untreated LDL greater than 500mg/dL AND presence of cutaneous and tendon xanthomas and corneal arcus in first decade of life. Must have chart documentation of clinical work-up to rule out other diagnoses. For initial auth: baseline negative pregnancy test with date of test and be on effective contraception for females of reproductive potential, and baseline laboratory monitoring of LDL, total cholesterol, triglycerides, transaminases, alkaline phosphatase, and bilirubin with date of test. Must be on statin (e.g. atorvastatin, simvastatin) unless intolerant or contraindicated and another LDL-lowering medication from a different class (e.g. ezetimibe, colestipol) prior to starting lomitapide. For reauth: documentation from prescriber indicating improvement in condition, documentation of follow-up LDL levels showing reduction in LDL level since starting treatment, and documentation of monitoring of transaminase, alkaline phosphatase, and bilirubin levels.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Lipidologist, cardiologist, endocrinologist, or geneticist

PA Criteria	Criteria Details
Coverage Duration	Initial: 120 days. Reauth: 365 days.
Other Criteria	If clinical documentation confirms the member meets the prior authorization criteria, lomitapide will be approved after consultation with a Medical Director.

KALYDECO

Products Affected

- Kalydeco oral granules in packet
- Kalydeco oral tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Documentation of lab result confirming at least one copy of one of the following mutations in CFTR gene: G551D, G1244E, G1349D, G178R, G551S, R117H, S1251N, S1255P, S549N, or S549R. Baseline percent of predicted FEV1. For reauth: must have documentation from prescriber showing member benefit from treatment, clinical rationale to support continuation of therapy, and current percent predicted FEV1.
Age Restrictions	Granules: age 2 years or older. Tablets: age 6 years or older.
Prescriber Restrictions	Cystic Fibrosis specialist
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

KANUMA

Products Affected

- Kanuma

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Allergy or sensitivity to eggs or egg products.
Required Medical Information	Diagnosis. Confirmation of genetic defect in the LIPA gene. For Lysosomal Acid Lypase (LAL) deficiency (Wolman disease): Documentation of growth failure not contributed to other causes and evidence of rapidly progressive disease confirmed via CT scan, MRI, or biopsy (such as hepatosplenomegaly, ascites, calcification of adrenal gland tissue, liver fibrosis confirmed through biopsy). For Cholesteryl Ester Storage Disease (CESD): documentation of the following- LDL-c greater than or equal to 130 mg/dL in pediatrics or greater than or equal to 160 mg/dl in adults, malabsorption and growth failure not contributed to other causes, calcification of adrenal gland tissue confirmed via CT scan or MRI, anemia (males greater than 12 years- Hgb less than 12 g/dl, females greater than 12 years- Hgb less than 11 g/dL, children 2 to 12 years- Hgb less than 10.5 g/dl, children 6 months to 2years- Hgb less than 9.5 g/dL), hepatomegaly confirmed via CT scan or MRI (liver size greater than or equal to 1.25 times normal), and splenomegaly (splenic mass greater than normal). For reauth: must have chart documentation that the condition has improved while on therapy.
Age Restrictions	Rapidly progressive lysosomal acid lypase (LAL) deficiency (Wolman disease): Age 1 month or older
Prescriber Restrictions	By or in consultation with a gastroenterologist, geneticist, lipidologist, or metabolic disorders specialist
Coverage Duration	365 days
Other Criteria	Not Applicable

KEVEYIS

Products Affected

- Keveyis

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Concomitant use with high dose aspirin. Severe pulmonary disease, limiting compensation to metabolic acidosis that may be caused by dichlorphenamide. Hepatic encephalopathy.
Required Medical Information	For primary hypokalemic periodic paralysis: must have documentation confirming diagnosis, defined as one of the following scenarios: two or more attacks of muscle weakness with documented serum K less than 3.5mEq/L, or one attack of muscle weakness in the member with documented serum potassium less 3.5mEq/L and one attack of weakness in a relative with a hx of the condition, or three of the following clinical/laboratory features: onset of symptoms in the first or second decade of life, duration of attack (muscle weakness involving one or more limbs) longer than two hours, presence of triggers (previous carbohydrate rich meal, symptom onset during rest after exercise or during stressful situations) for attacks, improvement in symptoms with potassium intake, family hx of the condition or genetically confirmed skeletal calcium or sodium channel mutation, positive long exercise test. For hyperkalemic periodic paralysis: must have documentation confirming diagnosis based on genetics or clinical presentation (see other coverage criteria).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Initial 90 days. Reauth: 365 days.
Other Criteria	For primary hypokalemic periodic paralysis: must have documentation excluding other causes of hypokalemia (renal, adrenal, thyroid dysfunction, renal tubular acidosis, diuretic and laxative abuse) and must currently be using a potassium supplement. For hyperkalemic periodic paralysis confirmed based on genetics testing: must have both of the following: family hx of the condition or genetically confirmed skeletal sodium channel mutation associated with hyperkalemic periodic paralysis and a hx of at least two attacks of flaccid limb weakness (which may also include weakness of the muscles of the eyes, throat, and trunk) or 1 attack

PA Criteria	Criteria Details
	with a family hx of attacks of hyperkalemic periodic paralysis. For hyperkalemic periodic paralysis confirmed based on clinical presentation must have all of the following: a hx of at least two attacks of flaccid limb weakness (which may also include weakness of the muscles of the eyes, throat, and trunk) or 1 attack with a family hx of attacks of hyperkalemic periodic paralysis, serum potassium greater than 5mEq/L or an increase of serum potassium concentration of at least 1.5 mEq/L during an attack of weakness and/or onset/worsening of an attack as a result of oral potassium intake, and presence of myotonia or any 3 of the following clinical features: typical attack duration less than 2 hours, onset before 30 years, positive long exercise test (greater than 40% decrement in CMAP), or typical external triggers (rest after exercise, potassium load, fasting). For hyperkalemic periodic paralysis: must have documentation of normal serum potassium concentration and muscle strength between attacks and electroencephalogram (ECG) recording for the exclusion of long QTc interval and ventricular arrhythmias. For hyperkalemic periodic paralysis: must not have secondary hyperkalemic periodic paralysis due to ingestion of potassium or of a potassium sparing diuretic or paramyotonia (i.e. muscle stiffness that is worsening after exercise or cold-induced). For hyperkalemic periodic paralysis must have documentation of exclusion of other hereditary forms of hyperkalemia (i.e., Andersen-Tawil syndrome) and acquired forms of hyperkalemia (drug abuse, renal and adrenal dysfunction). For reauth: must have documentation from prescriber indicating improvement in condition.

KINERET

Products Affected

- Kineret

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with anakinra.
Required Medical Information	Diagnosis. Must have negative tuberculosis skin test. Must have recent ANC. For RA: must have moderately to severely active RA, must have adequate trial and failure of etanercept and adalimumab with inadequate response or significant side effects/toxicity unless contraindicated. For cryopyrin-associated periodic syndromes: must have neonatal-onset multisystem inflammatory disease, must have chart doc of diagnosis confirmed by genetic test (must have documentation of lab result confirming mutation in NLRP3 gene) or a clinical diagnosis (must have 2 of the following: urticarial rash, fever, epiphyseal or patellar overgrowth on radiography, ocular involvement, CNS involvement). For reauth: must have documentation from prescriber indicating improvement in condition and that ANC is being monitored consistently.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Rheumatologist or pediatrician
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

KISQALI

Products Affected

- Kisqali

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

KORLYM

Products Affected

- Korlym

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Pregnant. History of unexplained vaginal bleeding, endometrial hyperplasia with atypia, or endometrial carcinoma. Concomitant therapy with simvastatin, lovastatin, or CYP3A4 substrates with narrow therapeutic range (i.e. cyclosporine, tacrolimus). Concurrent long-term corticosteroid treatment.
Required Medical Information	Diagnosis. Must have failed surgery or not be a candidate for surgery (trans-sphenoidal surgery for pituitary dependent Cushing's or surgical removal of an adrenocortical tumor or a source of ectopic ACTH in malignant Cushing's). Female members of reproductive potential: must have baseline (within previous month, must include date of test) negative pregnancy test prior to starting mifepristone and must be using non-hormonal medically acceptable method of contraception (unless surgically sterilized) during treatment and for 1 month after mifepristone therapy. Must have baseline hemoglobin A1C level. Must have chart documentation of an adequate trial and failure of conventional anti-hyperglycemic medication. For reauth: must have documentation from prescriber indicating improvement in condition, must have documentation of recent (within previous month) negative pregnancy test including date of test if female of reproductive potential, and must have documentation of improvement in hyperglycemia control as evidenced by a reduction in blood glucose levels, HbA1c, or anti-hyperglycemic medication doses or number of medications.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with an endocrinologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

KUVAN

Products Affected

- Kuvan

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Baseline serum phenylalanine level. For reauth: must have documentation from prescriber indicating response to therapy, follow-up serum phenylalanine level.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Initial: 60 days. Reauth: 365 days.
Other Criteria	Continuation/Discontinuation criteria: lab reassessment will be conducted after an initial one month trial to determine if authorization may be extended. Patients on the 10mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month of treatment should increase to 20mg/kg/day. These patients will be approved for another one month trial at the higher dose. Patients on the 20mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month are considered non-responders, and treatment with Kuvan should be discontinued in these patients.

KYNAMRO

Products Affected

- Kynamro

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Severe hepatic impairment or active liver disease
Required Medical Information	Diagnosis of homozygous familial hypercholesterolemia confirmed by genetic testing with functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality or have clinical diagnosis defined as one of the following (1) untreated LDL greater than 500mg/dL AND untreated total cholesterol (TC) greater than 500mg/dL and triglycerides (TG) less than 300mg/dL with both parents with untreated TC greater than 250mg/dL, (2) skin fibroblast LDL receptor activity less than 20% of normal AND untreated TC greater than 500mg/dL and TG less than 300mg/dL with both parents with untreated TC greater than 250mg/dL, (3) presence of cutaneous and tendon xanthomas and corneal arcus in first decade of life AND untreated TC greater than 500mg/dL and TG less than 300mg/dL with both parents with untreated TC greater than 250mg/dL, (4) untreated LDL greater than 500mg/dL AND skin fibroblast LDL receptor activity less than 20% of normal, (5) untreated LDL greater than 500mg/dL AND presence of cutaneous and tendon xanthomas and corneal arcus in first decade of life. Must have chart documentation of clinical work-up to rule out other diagnoses. For initial auth: baseline laboratory monitoring of LDL, total cholesterol, triglycerides, transaminases, alkaline phosphatase, and bilirubin with date of test. Must be on statin (e.g. atorvastatin, simvastatin) unless intolerant or contraindicated and another LDL-lowering medication from a different class (e.g. ezetimibe, colestipol) prior to starting mipomersen. For reauth: documentation from prescriber indicating improvement in condition, documentation of follow-up LDL levels showing reduction in LDL level since starting treatment, and documentation of monitoring of transaminase, alkaline phosphatase, and bilirubin levels.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Lipidologist, cardiologist, or endocrinologist
Coverage	Initial: 180 days. Reauth: 365 days.

PA Criteria	Criteria Details
Duration	
Other Criteria	If clinical documentation confirms the member meets the prior authorization criteria, mipomersen will be approved after consultation with a Medical Director.

LENVIMA

Products Affected

- Lenvima oral capsule 10 mg/day (10 mg x 1/day), 14 mg/day(10 mg x 1-4 mg x 1), 18 mg/day (10 mg x 1-4 mg x2), 20 mg/day (10 mg x 2), 24 mg/day(10 mg x 2-4 mg x 1), 8 mg/day (4 mg x 2)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

LETAIRIS

Products Affected

- Letairis

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of PAH (WHO Group I) confirmed diagnosis by right heart catheterization. Must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than or equal to 25 mmHg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than 3 Wood units. Must have baseline negative pregnancy prior to initiation of therapy if a female of child-bearing potential. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Cardiologist or pulmonologist. Combination therapy with two or more PAH agents must be prescribed by or in consultation with a pulmonary hypertension specialist.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

LEUKINE

Products Affected

- Leukine injection recon soln

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For AML: must be receiving induction chemotherapy. For bone marrow transplant, must have one of the following: must require administration after autologous (not allogeneic) bone marrow transplant for NHL/ALL/Hodgkin's disease, must require mobilization of progenitor cells into peripheral blood (often in conjunction with chemotherapy) for collection by leukophoresis, must have undergone allogeneic bone marrow transplant from HLA-matched related donor, OR must have undergone allogeneic or autologous bone marrow transplantation where engraftment is delayed or has failed. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	AML: age 55 years or older. BMT: age 18 years or older.
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	90 days
Other Criteria	Not Applicable

LEUPROLIDE AND DERIVATIVES

Products Affected

- Eligard
- Eligard (3 month)
- Eligard (4 month)
- Eligard (6 month)
- Firmagon kit w diluent syringe subcutaneous recon soln 120 mg, 80 mg
- leuprolide subcutaneous kit
- Lupaneta Pack (1 month)
- Lupaneta Pack (3 month)
- Lupron Depot
- Lupron Depot (3 Month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)
- Lupron Depot-Ped intramuscular kit 11.25 mg, 15 mg
- Synarel
- Trelstar intramuscular suspension for reconstitution 22.5 mg
- Trelstar intramuscular syringe 11.25 mg/2 mL, 3.75 mg/2 mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For endometriosis: must have diagnosis confirmed by laproscopy OR chart documentation of clinical work-up and clinical rationale for diagnosis, and must have trial and failure of oral contraceptives and/or progestins for mild disease. For fibroids: must be used preoperatively to maximize hemoglobin in patients with documented anemia (Hgb less than 11g/dL), or preoperatively to decrease size of fibroid uterus so less invasive route of hysterectomy can be attempted, or must provide clinical rationale if using outside context of preoperative adjuvant therapy in the surgical management of fibroids. For central precocious puberty: must have onset of secondary sexual characteristics earlier than age 8 years in females and 9 years in males. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Central Precocious Puberty: only be approved up to age 11 years in females and age 12 years in males
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Cancer, CPP: 365 dys. Endometriosis: 180 dys. Fibroid: 90 dys.
Other Criteria	Not Applicable

LIDOCAINE PATCH

Products Affected

- lidocaine topical adhesive patch,medicated

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

LONSURF

Products Affected

- Lonsurf

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. ECOG Performance Status.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

LYNPARZA

Products Affected

- Lynparza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming BRCA mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

LYRICA

Products Affected

- Lyrica oral capsule 100 mg, 150 mg, 200 mg, 225 mg, 25 mg, 300 mg, 50 mg, 75 mg
- Lyrica oral solution

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For fibromyalgia: must have chart documentation of diagnosis with history of widespread pain involving extremities for 3 months and localized area of tenderness, must have trial and failure of or intolerance to gabapentin at a dose of at least 1200mg/day AND either a tricyclic antidepressant or muscle relaxant unless contraindicated, and must have history of physician-directed exercise program or physical therapy. For PHN: must have trial and failure of gabapentin or a tricyclic antidepressant. For DPN: must have documented pharmacy claim history or prior therapy with a diabetic medication OR a medical/lab claim or physician chart note of diabetes diagnosis, must have trial and failure of gabapentin.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

MAKENA

Products Affected

- Makena intramuscular oil 250 mg/mL (1 mL)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Current or history of thrombosis or thromboembolic disorders. Known or suspected breast cancer or other hormone-sensitive cancer or history of these disorders. Undiagnosed abnormal vaginal bleeding unrelated to pregnancy. Cholestatic jaundice of pregnancy. Liver tumors (benign or malignant) or active liver disease. Uncontrolled hypertension
Required Medical Information	Diagnosis of singleton pregnancy. History of singleton spontaneous preterm birth. Must be starting or have started treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	22 weeks
Other Criteria	Not Applicable

MEGESTROL

Products Affected

- megestrol oral suspension 400 mg/10 mL (40 mg/mL)
- megestrol oral tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist, hematologist, or HIV specialist
Coverage Duration	365 days
Other Criteria	Not Applicable

MEKINIST

Products Affected

- Mekinist oral tablet 0.5 mg, 2 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Treatment with prior BRAF-inhibitor therapy if using trametinib as monotherapy
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming BRAFV600E or BRAFV600K mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

MEMANTINE

Products Affected

- memantine oral solution
- memantine oral tablet
- memantine oral tablets,dose pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of moderate to severe dementia of Alzheimer's type.
Age Restrictions	Must be age 18 or older. Age 18 to 40 years: criteria apply. Age greater than 40 years: criteria do not apply.
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

METHOXSALEN

Products Affected

- methoxsalen oral

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For psoriasis: must have severe, recalcitrant, disabling psoriasis confirmed by biopsy, must use in conjunction with UVA light therapy, and must have an adequate trial of 2 topical treatments (e.g. calcipotriene, fluocinonide, bethamethasone, hydrocortisone, clobetasol propionate) with an inadequate response or significant side effects /toxicity or have a contraindication. For cutaneous T-cell lymphoma: must use with UVAR system. For vitiligo: must use in conjunction with UVA light therapy and must have an adequate trial of calcipotriene with an inadequate response or significant side effect/toxicity or have a contraindication. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Psoriasis, vitiligo: dermatologist. Cutaneous T-cell lymphoma: dermatologist or oncologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

MODAFINIL

Products Affected

- modafinil

PA Criteria	Criteria Details
Covered Uses	All medically-accepted indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Chart documentation of sleep study confirming diagnosis for narcolepsy and OSA. For narcolepsy: must have adequate trial and failure of CNS stimulant (e.g. amphetamine salts, dextroamphetamine, methylphenidate). For shift-work sleep disorder (SWSD): must meet International Classification of Sleep Disorders criteria for SWSD (either primary complaint of excessive sleepiness or insomnia temporarily associated w/ work period that occurs during habitual sleep phase OR polysomnography and Multiple Sleep Latency Test demonstrate loss of normal sleep-wake pattern, no other medical or mental disorders account for symptoms, and symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness such as time zone change syndrome) and must provide chart documentation of shift work schedule showing 5 or more night shifts per month (defined as at least 4 hours of shift occurring between 10pm and 8am). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	SWSD: 180 days. Narcolepsy, OSA: 365 days.
Other Criteria	Not Applicable

MOLINDONE

Products Affected

- molindone

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have an adequate trial and failure or an inadequate response or intolerance to 2 generic antipsychotics (e.g., haloperidol, fluphenazine, chlorpromazine, perphenazine, aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

MOZOBIL

Products Affected

- Mozobil

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of Non-Hodgkin's Lymphoma or multiple myeloma and require hematopoietic stem cell mobilization for collection and subsequent autologous transplantation. Must be used in combination with granulocyte colony stimulating factor (G-CFS) and be initiated after receipt of G-CFS daily for 4 days. Must have documentation that plerixafor will be administered 11 hours prior to initiation of apheresis for up to 4 consecutive days. For reauth: must meet initial auth criteria.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Bone marrow transplant specialist, hematologist, or oncologist
Coverage Duration	4 days
Other Criteria	Not Applicable

MYALEPT

Products Affected

- Myalept

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	HIV-related lipodystrophy
Required Medical Information	Diagnosis. Must have chart documentation of a clinical work-up to rule out other diagnoses and clinical rationale for the diagnosis and exclusion of other diagnoses. Must have severe insulin resistance resulting in diabetes mellitus (a hemoglobin A1c of at least 7% or fasting plasma glucose of at least 126mg/dL) with chart documentation showing an adequate trial of diabetic pharmacotherapy (such as with an insulin product) that did not allow the member to achieve adequate glucose control with optimized medication regimen AND/OR must have severe hypertriglyceridemia (triglyceride level of at least 500mg/dL) with chart documentation of an adequate trial of lipid-lowering pharmacotherapy (such as a fibrate, omega-3 fatty acid, or statin) that did not allow the member to achieve adequate triglyceride control with optimized medication regimen. For reauth: must have documentation from prescriber indicating benefit with metreleptin treatment (as evidenced by decrease in hemoglobin A1c, fasting plasma glucose, and/or triglyceride levels from baseline).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Endocrinologist
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

MYOZYME AND LUMIZYME

Products Affected

- Lumizyme

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Confirmed diagnosis of alpha glucosidase deficiency (Pompe disease). For reauth: must have documentation from prescribing indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration	365 days
Other Criteria	Not Applicable

MYTESI

Products Affected

- Mytesi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must be actively utilizing antiretroviral agents to treat HIV/AIDS. Must have documentation of persistent loose stools despite regular use of at least one anti-diarrheal medication (e.g. loperamide, diphenoxylate/atropine). For reauth: must have documentation from prescriber indicating improvement in condition, decrease in number of watery bowel movements, and continuous use of antiretroviral agents for HIV/AIDS.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	HIV or infectious disease specialist
Coverage Duration	Initial: 30 days. Reauth: 180 days.
Other Criteria	Not Applicable

NAGLAZYME

Products Affected

- Naglazyme

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 3 months or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

NATPARA

Products Affected

- Natpara

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Pagets disease of the bone or unexplained elevations of alkaline phosphatase, hereditary disorders predisposing to osteosarcoma or prior external beam or implant radiation therapy involving the skeleton. Hypoparathyroidism caused by calcium-sensing receptor mutations. Acute (less than 6 months) post-surgical hypoparathyroidism.
Required Medical Information	Diagnosis. Must have chart documentation of a laboratory report (including reference range) of a recent parathyroid hormone level below the lower limit of normal. Must have uncontrolled hypocalcemia while on concomitant calcium and vitamin D confirmed by chart documentation of a laboratory report (including reference range) of a recent calcium level below the lower limit of normal. Must have a baseline serum calcium concentration greater than 7.5mg/dL prior to initiating parathyroid hormone (Natpara) therapy. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Endocrinologist
Coverage Duration	365 days
Other Criteria	Not Applicable

NEULASTA

Products Affected

- Neulasta subcutaneous syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must be receiving chemo regimen with dosing frequency of once every 2 wks or greater. For primary prophylaxis of febrile neutropenia (FN): must be receiving either myelosuppressive chemo regimen with greater than 20% risk of FN (per ASCO or NCCN guidelines) or non-myelosuppressive chemo regimen (less than or equal to 20% risk of FN) and considered to be at high risk for chemo-induced FN or infection with at least one risk factor (age 65 years or older, poor performance status, previous episode of FN, extensive prior treatment including large radiation ports, previous chemotherapy or radiation therapy, pre-existing neutropenia, cytopenia due to bone marrow involvement by tumor, poor nutritional status, presence of open wounds or active infection, recent surgery, advanced cancer, liver dysfunction such as elevated bilirubin, or other serious comorbidities). For secondary prophylaxis of FN: must have experienced a neutropenic complication from prior chemo cycle for which primary prophylaxis was not received and in which reduced dose may compromise disease-free or overall survival or treatment outcome. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	90 days
Other Criteria	Not Applicable

NEUPOGEN

Products Affected

- Granix
- Neupogen
- Zarxio

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D and diagnoses of agranulocytosis and myelodysplastic syndrome
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Primary prophylaxis of FN: must be receiving myelosuppressive chemo with greater than 20% FN risk OR non-myelosuppressive chemo (less than or equal to 20% FN risk) and considered high risk for chemo-induced FN or infection with at least 1 risk factor (see other criteria) OR dose-dense chemo for tx of node + breast ca, small-cell lung ca, or diffuse aggressive Non-Hodgkin's Lymphoma. Secondary prophylaxis of FN: must have experienced neutropenic complication from prior chemo cycle for which primary prophylaxis not received and in which reduced dose may compromise disease-free or overall survival or tx outcome. Tx of febrile pts w/ neutropenia: must have fever and neutropenia and be at high risk for infection-related complications or have prognostic factors predictive of poor clinical outcomes, have at least one risk factor (see other criteria), AND not have received prophylactic pegfilgrastim during current chemo cycle. Bone marrow txfr: must be used after autologous peripheral blood progenitor cell transplant OR mobilization of progenitor cells into peripheral blood (often in conjuction with chemo) for collection by leukophoresis. AML: must be receiving induction or consolidation tx. ALL: must be using after completion of initial 1st few days of chemo of initial induction or 1st post-remission course. Myelodysplastic syndrome: must have severe neutropenia and recurrent infection. Pts receiving radiation: must be receiving radiation tx w/o concomitant chemo w/ expected prolonged delays due to neutropenia. Older lymphoma pts: must have dx of acute aggressive lymphoma tx w/ curative chemo (CHOP or more aggressive regimen). Congenital, cyclic, or idiopathic neutropenia: must have symptomatic neutropenia. Drug-induced agranulocytosis: must have severe neutropenia w/ fever or serious infection as result of myelosuppressive regimen. For reauth: must have doc from prescriber indicating improvement in condition.
Age Restrictions	Neupogen, Zarxio: no age restrictions. Granix: age 18 years or older.

PA Criteria	Criteria Details
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	90 days
Other Criteria	% risk of FN based on ASCO or NCCN guidelines. Risk factors for primary prophy of FN: age 65 years or older, poor performance status, previous episode of FN, extensive prior treatment including large radiation ports, previous chemotherapy or radiation therapy, pre-existing neutropenia, cytopenia due to bone marrow involvement by tumor, poor nutritional status, presence of open wounds or active infection, recent surgery, advanced cancer, liver dysfunction such as elevated bilirubin, or other serious comorbidities. Risk factors for tx of febrile pts w/ neutropenia: sepsis syndrome, expected prolonged neutropenia for greater than 10 days, severe neutropenia with ANC less than 100/microliter, age 65 years or older, uncontrolled primary disease, pneumonia, hypotension and multi-organ dysfunction (sepsis syndrome), invasive fungal infection, other clinically documented infections, hospitalization at time of fever, prior episode of febrile neutropenia. For treatment of febrile patients w/ neutropenia: must not have received pegfilgrastim during current chemotx cycle.

NEUPRO

Products Affected

- Neupro

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For Parkinson's disease: must have adequate trial and failure of pramipexole or ropinirole. For Restless Legs Syndrome: must have moderate to severe dx, must have adequate trial and failure of pramipexole or ropinerole (defined as insufficient efficacy of pramipexole 0.5mg per day or ropinirole 4mg per day, intolerance to a lower dose of one of these medications, or contraindication) AND must have adequate trial and failure of gabapentin.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

NEXAVAR

Products Affected

- Nexavar

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

NINLARO

Products Affected

- Ninlaro oral capsule 2.3 mg, 3 mg, 4 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

NORTHERA

Products Affected

- Northera oral capsule 100 mg, 200 mg, 300 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of symptomatic neurogenic hypotension caused by 1 of following: primary autonomic failure (e.g. Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy. Must have chart doc showing how diagnosis made, incl BP readings showing systolic blood pressure decrease of at least 20mmHg or diastolic blood pressure decrease of at least 10mmHg within 3 minutes of standing. Must have doc that member is symptomatic as result of low BP readings, including doc to support that member is experiencing at least 1 of the following symptoms: dizziness, lightheadedness, feeling faint, feeling like might black out. Must have chart doc indicating d/c or dose decrease of drugs which can cause orthostatic hypotension such as anti-hypertensives, nitrates, alpha-1 blockers (i.e. terazosin, prazosin), antiparkinsonian agents (i.e. levodopa, bromocriptine, ropinirole, pramipexole), diuretics, monoamine oxidase inhibitors, narcotics/tranquilizers/sedatives, drugs for erectile dysfunction, tricyclic antidepressants. Must have an adequate trial of midodrine. For reauth: must have doc from prescriber indicating improvement in condition as evidenced by improvement in the symptoms member was experiencing (i.e. dizziness, lightheadedness, feeling faint, or feeling like might black out) and showing member is being monitored for adverse effects (i.e. supine hypertension) and additional drugs have not been added to the drug regimen that would cause supine hypertension.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Cardiologist or neurologist
Coverage Duration	Initial: 1 month. Reauth: 6 months.
Other Criteria	Not Applicable

NOXAFIL

Products Affected

- Noxafil oral suspension
- Noxafil oral tablet,delayed release (DR/EC)

PA Criteria	Criteria Details
Covered Uses	All medically-accepted indications not otherwise excluded from Part D
Exclusion Criteria	Members on the following medications: terfenadine, astemizole, cisapride, pimozide, halofantrine, quinidine, sirolimus.
Required Medical Information	Diagnosis. For prophylaxis of Aspergillis and Candida infections (tablet, injection, or suspension): must be severly immunocompromised. For treatment of oropharyngeal candidaisis (suspension): must have trial and failure of fluconazole and/or itraconazole for at least 2 weeks. For reauth: must have documentation from prescriber indicating clinical rationale for retreatment.
Age Restrictions	Injection: age 18 years or older, Tablet or suspension: age 13 years or older.
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Prophy of Aspergillis/Candida: 120 dys. Oropharyngeal Candidiasis: 30 dys.
Other Criteria	Not Applicable

NUCALA

Products Affected

- Nucala

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have severe persistent asthma. Must have blood eosinophil count of greater than 150 cells/uL within the past six weeks (while on corticosteroid) or greater than or equal to 300 cells/uL within past year, including date test performed. Must have adequate trial of combination therapy with an ICS/LABA (inhaled corticosteroid/long-acting beta-agonist, such as Advair, Breo Ellipta, or Dulera) AND either a LAMA (long-acting muscarinic antagonist, such as Spiriva or Incruse Ellipta) or a leukotriene receptor antagonist (such as montelukast) with inadequate response or significant side effects/toxicities or have a contraindication to these therapies. Must have asthma symptoms that continue to be uncontrolled on optimized medication therapy regimen (uncontrolled defined as hospitalization for asthma within past year, requirement for oral or parenteral corticosteroids to control exacerbations of asthma on 2 occurrences in the past year, or need for daily corticosteroid with inability to taper off). For reauth: must have documentation from prescriber indicating improvement in condition (such as reduced exacerbations, hospitalizations, emergency department visits, or requirement for oral corticosteroid therapy).
Age Restrictions	Age 12 years or older
Prescriber Restrictions	By or in consultation with an allergist, an immunologist, or a pulmonologist
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

NUEDEXTA

Products Affected

- Nuedexta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Members on quinidine, quinine, mefloquine, MAOIs in the last 14 days, drugs that prolong the QT interval and are metabolized by CYP2D6. History of hypersensitivity to quinidine, quinine, mefloquine, or dextromethorphan. Diagnosis of prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, heart failure, complete AV (atrioventricular) block without an implanted pacemaker, or high risk of complete AV block
Required Medical Information	Diagnosis of pseudobulbar affect (PBA) supported by chart documentation of the following: involuntary outbursts of laughing and/or crying that are incongruous or disproportionate to the patient's emotional state AND documentation of a clinical work-up, including clinical rationale for the PBA diagnosis and exclusion of other possible conditions that could result in emotional lability (e.g. depression, bipolar disorder, schizophrenia, epilepsy). Must have underlying neurological disorder such as amyotrophic lateral sclerosis, multiple sclerosis, Alzheimer's and related diseases, Stroke, Traumatic Brain Injury, or Parkinsonian Syndrome. For reauth: must have documentation from prescriber indicating decrease in number of laughing and/or crying episodes as a result of therapy.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with neurologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

NULOJIX

Products Affected

- Nulojix

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection, including, but not limited to: Progressive multifocal leukoencepalopathy, Cytomegalovirus, Polyoma virus-associated neuropathy. History of or currently active malignancy.
Required Medical Information	Diagnosis. Negative tuberculosis skin test. EBV seropositive as demonstrated by EBV serology. Must be undergoing or have undergone renal transplant. Must be at increased risk of renal failure before transplant OR must have tried and failed or have intolerance to tacrolimus or cyclosporine unless contraindicated. Must be used in conjunction with basiliximab induction if given at time of transplant, mycophenolate mofetil, and corticosteroids.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Physician who specializes in immunosuppression or renal transplantation.
Coverage Duration	365 days
Other Criteria	B vs. D determination will be made prior to clinical criteria being applied.

NUPLAZID

Products Affected

- Nuplazid

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must provide chart documentation of clinical work-up to rule out other diagnoses. Clinical rationale for diagnosis and exclusion of other diagnoses must be provided. Must have tried to discontinue or reduce the dose of any medication(s) that may cause or contribute to hallucinations and delusions (i.e. dopamine agonists, amantadine, monoamine oxidase B inhibitors, anticholinergics) or provide clinical rationale indicating why dose reduction or discontinuation of applicable medications would not be appropriate.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a psychiatrist or neurologist that specializes in the treatment of movement disorders
Coverage Duration	365 days
Other Criteria	Not Applicable

OCALIVA

Products Affected

- Ocaliva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Complete biliary obstruction
Required Medical Information	Diagnosis. Must have a diagnosis of primary biliary cholangitis (PBC) defined by meeting at least two of the following criteria: 1) chart doc of lab result showing elevated alkaline phosphatase (ALP) above the upper limit of normal (ULN) for at least 6 months based on the reference range provided by lab, 2) positive anti-mitochondrial antibody (AMA) titer, 3) liver biopsy consistent with PBC. Must have an adequate trial of at least 12 months with ursodiol at a dose of 13-15 mg/kg/day with an inadequate response (defined as ALP 1.5-times the ULN) or intolerance at any dose or must have a contraindication to ursodiol. Must be used in combination with ursodiol unless clinically contraindicated or intolerant to ursodiol. For reauth: Must have documentation from provider showing disease has improved while on therapy and monitoring of liver function tests occuring annually.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with a gastroenterologist, hepatologist, or liver transplant specialist
Coverage Duration	365 days
Other Criteria	Not Applicable

ODOMZO

Products Affected

- Odomzo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ONFI

Products Affected

- Onfi oral suspension
- Onfi oral tablet 10 mg, 20 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of Lennox-Gastaut syndrome. Must have had an inadequate response or intolerance to 2 generic antiepileptic drugs (e.g. lamotrigine, topiramate, felbamate) and be using clobazam as adjunctive therapy to other anti-epileptic drugs.
Age Restrictions	Age 2 years or older
Prescriber Restrictions	By or in consultation with a neurologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

ONMEL

Products Affected

- Onmel

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Immunocompromised member
Required Medical Information	Diagnosis. Must have onychomycosis of toenail due to Trichophyton rubrum or T. mentagrophytes causing severe, debilitating foot pain supported by chart documentation. Must provide chart documentation of laboratory testing of nail specimen (such as KOH preparation, fungal culture, or nail biopsy). Must have documentation of trial and failure of itraconazole capsules for at least 1 full course of treatment (3 months). For reauth: based upon diagnosis and must have documentation of response to previous course of treatment with itraconazole tablets (Onmel).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	90 days
Other Criteria	Not Applicable

OPSUMIT

Products Affected

- Opsumit

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of PAH (WHO Group I) confirmed by right heart catheterization. Must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than or equal to 25 mmHg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than 3 Wood units. Must have baseline hemoglobin and liver function tests (AST, ALT) prior to initiation of therapy. Must have baseline negative pregnancy prior to initiation of therapy if a female of child-bearing potential. Must have previous inadequate response or intolerance to ambrisentan (Letairis). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Cardiologist or pulmonologist. Combination therapy with two or more PAH agents must be prescribed by or in consultation with a pulmonary hypertension specialist.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

ORALAIR

Products Affected

- Oralair sublingual tablet 300 indx reactivity

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	History of any severe systemic allergic reaction. History of eosinophilic esophagitis. Severe, unstable or uncontrolled asthma. On concomitant immunotherapy.
Required Medical Information	Diagnosis. Must have moderate to severe grass pollen-induced allergic rhinitis with or without conjunctivitis. Must have diagnosis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens (i.e. Sweet Vernal, Orchard, Perennial Rye, Kentucky Blue Grass) and chart documentation demonstrating seasonal symptoms to grass-pollen from the previous pollen season. Must have chart documentation demonstrating daily concomitant use of an inhaled nasal corticosteroid (i.e. fluticasone) and an oral antihistamine (i.e. levocetirizine) during the previous pollen season with inadequate responses or significant side effects/toxicities or have contraindication to these therapies. Must have plan for first dose to be administered in physician office due to potential for life-threatening allergic reactions, including anaphylaxis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 10 years through 65 years
Prescriber Restrictions	Allergist or immunologist
Coverage Duration	180 days
Other Criteria	Therapy must be initiated 4 months prior to the onset of grass pollen season.

ORENCIA IV

Products Affected

- Orencia (with maltose)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with abatacept.
Required Medical Information	Diagnosis. Must have negative tuberculosis skin test. Must have moderately to severely active RA or JIA. Must have adequate trial of methotrexate with inadequate response OR must have adequate trial of leflunomide, hydroxychloroquine, or sulfasalazine with an inadequate response or significant side effect/toxicity or must have a contraindication to these therapies if an adequate trial of methotrexate is not possible (e.g. due to significant side effects/toxicities or a contraindication to methotrexate). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	JIA: age 6 years or older. RA: age 18 years or older.
Prescriber Restrictions	Rheumatologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ORENCIA SYRINGE

Products Affected

- Orencia
- Orencia ClickJect

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with abatacept.
Required Medical Information	Diagnosis. Must have negative tuberculosis skin test. Must have moderately to severely active RA. Must have adequate trial of etanercept and adalimumab with inadequate response or significant side effect/toxicity unless contraindicated. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 6 years or older
Prescriber Restrictions	Rheumatologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ORFADIN

Products Affected

- Orfadin oral capsule 10 mg, 2 mg, 5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of Hereditary Tyrosinemia Type 1. Laboratory test of baseline succinylacetone (SA) level, liver evaluation, and ophthamalogic testing. For reauth: must have documentation from prescriber indicating improvement in condition, monitoring for hematologic and hepatic side effects, and laboratory test demonstrating progressive SA suppression.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a gastroenterologist, hematologist, nephrologist, or physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

ORFADIN SUSPENSION

Products Affected

- Orfadin oral suspension

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of Hereditary Tyrosinemia Type 1. Laboratory test of baseline succinylacetone (SA) level, liver evaluation, and ophthamalogic testing. Must have chart documentation of the clinical rationale for why nitisinone capsule cannot be used. For reauth: must have documentation from prescriber indicating improvement in condition, monitoring for hematologic and hepatic side effects, and laboratory test demonstrating progressive SA suppression.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a gastroenterologist, hematologist, nephrologist, or physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

ORKAMBI

Products Affected

- Orkambi oral tablet 100-125 mg, 200-125 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Documentation of lab result confirming the following mutation in CFTR gene: F508del. Baseline percent of predicted FEV1. For reauth: must have chart documentation from prescriber showing member benefit from treatment, clinical rationale to support continuation of therapy, and current percent predicted FEV1.
Age Restrictions	Age 6 years or older
Prescriber Restrictions	Cystic Fibrosis specialist
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

OTEZLA

Products Affected

- Otezla
- Otezla Starter oral tablets,dose pack 10 mg (4)-20 mg (4)-30 mg (47)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For psoriatic arthritis: must have active disease. For psoriasis: must have moderate to severe plaque psoriasis and must have minimum body surface area of at least 5% (not required if on palms, soles, head/neck, or genitalia). Must have adequate trials of etanercept and adalimumab with inadequate responses or significant side effects/toxicity unless contraindicated. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Psoriatic arthritis: rheumatologist or dermatologist. Psoriasis: dermatologist
Coverage Duration	365 days
Other Criteria	Not Applicable

OTREXUP AND RASUVO

Products Affected

- Otrexup (PF) subcutaneous auto-injector 10 mg/0.4 mL, 12.5 mg/0.4 mL, 15 mg/0.4 mL, 17.5 mg/0.4 mL, 20 mg/0.4 mL, 22.5 mg/0.4 mL, 25 mg/0.4 mL
- Rasuvo (PF) subcutaneous auto-injector 10 mg/0.2 mL, 12.5 mg/0.25 mL, 15 mg/0.3 mL, 17.5 mg/0.35 mL, 20 mg/0.4 mL, 22.5 mg/0.45 mL, 25 mg/0.5 mL, 27.5 mg/0.55 mL, 30 mg/0.6 mL, 7.5 mg/0.15 mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have an adequate trial of oral methotrexate or generically-available subcutaneous methotrexate with an inadequate response OR have had a significant side effect/toxicity. For Otrexup requests must have an adequate trial of Rasuvo with an inadequate response OR have had a significant side effect/toxicity. For reauth: must have documentation from the prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	RA, poylarticular JIA: rheumatologist. Psoriasis: dermatologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

OXANDROLONE

Products Affected

- oxandrolone

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Carcinoma of breast or prostate in male patients. Carcinoma of breast in female patients with hypercalcemia. Pregnancy. Nephrosis (i.e. nephrotic phase of nephritis). Hypercalcemia. Severe hepatic dysfunction.
Required Medical Information	Diagnosis. Must be used as adjunctive therapy to medically-accepted treatment for the diagnosis. For reauth: must have documentation from prescriber indicating improvement or stabilization in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Osteoporosis bone pain: endrocrinologist. Chronic infection: immunologist or infectious disease specialist.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

PALIPERIDONE

Products Affected

- paliperidone oral tablet extended release 24hr 1.5 mg, 3 mg, 6 mg, 9 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of schizophrenia or schizoaffective disorder. Must have adequate trial and failure of 2 oral atypical antipsychotics.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

PANRETIN

Products Affected

- Panretin

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must be on an antiretroviral regimen. For reauth: must have documentation from prescriber indicating stabilization or improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with a dermatologist, oncologist, or HIV specialist
Coverage Duration	365 days
Other Criteria	Not Applicable

PHEOCHROMOCYTOMA

Products Affected

- Demser

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have surgical resection planned, have a contraindication to surgery, or have malignant pheochromocytoma. For reauth: must have documentation from prescriber indicating stabilization or improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a nephrologist, oncologist, endocrinologist, or endocrine surgeon
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

PICATO

Products Affected

- Picato

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Initial auth: actinic keratosis must be present on face, scalp, trunk, or extremities and pt must have adequate trial of topical fluorouracil or imiquimod 5% with inadequate response unless intolerant or contraindicated. For reauth: must meet initial auth criteria and must have either clinical rationale from the prescriber for continuation of treatment at the same site or documentation that therapy is required at an alternative site.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with a dermatologist or oncologist
Coverage Duration	3 days
Other Criteria	Not Applicable

POMALYST

Products Affected

- Pomalyst oral capsule 1 mg, 2 mg, 3 mg, 4 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

POTIGA

Products Affected

- Potiga

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have adequate trials of 2 antiepileptic medications (e.g. carbamazepine, oxcarbazepine, or phenytoin). Must be using as adjunctive therapy to other anti-epileptic medications (which can include medication from trial above). Must have baseline ophthalmic exam prior to starting therapy with ezogabine.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	365 days
Other Criteria	Not Applicable

PRALUENT

Products Affected

- Praluent Pen

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have confirmed diagnosis of heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD). For ASCVD: must have chart documentation confirming history of at least one of the following: myocardial infarction or other acute coronary syndromes (including ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, and unstable angina), coronary or other revascularization procedure, ischemic stroke or transient ischemic attack, atherosclerotic peripheral arterial disease (includes ankle/brachial index of less than 0.90), coronary artery calcium greater than or equal to 300 Agatston units or greater than or equal to 75th percentile for age/sex/ethnicity, carotid plaque greater than or equal to 50%, coronary atherosclerosis as demonstrated by angiography (cardiac CT angiography or conventional cardiac catheterization). Must have baseline and target LDL-cholesterol levels. Must have LDL-C level above target despite adequate trial of 2 high intensity statins (atorvastatin 40-80mg daily and rosuvastatin 20-40mg daily), unless intolerant to statin treatment (defined as confirmed, intolerable statin-related adverse effects or biomarker abnormalities that improve or resolve with statin dose decrease or discontinuation) or statin treatment is contraindicated (defined as documented active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels). If able to tolerate statin, must continue treatment with statin at maximally tolerated dose. For reauth: must have documentation of: (1) recent assessment of LDL-C level with decrease and (2) continued treatment with maximally tolerated dose of a statin (if applicable).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a cardiologist or an endocrinologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.

PA Criteria	Criteria Details
Other Criteria	Not Applicable

PROLIA

Products Affected

- Prolia

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have trial and failure of bisphosphonate therapy unless intolerant or contraindicated. For postmenopausal osteoporosis in females or to increase bone mass in males with osteoporosis at high risk of fracture: must have bone mineral density T-score of less than or equal to -2.5 at conventional skeletal sites including the total hip, femoral neck, lumbar spine (post-anterior, not lateral) or radius OR must have history of fragility fracture as an adult. For females with breast cancer: must be receiving aromatase inhibitor therapy. For males with non-metastatic prostate cancer: must be receiving androgen deprivation therapy. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 Days
Other Criteria	Not Applicable

PROMACTA

Products Affected

- Promacta oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For ITP: must have platelet count less than 30,000. For thrombocytopenia associated with chronic Hepatitis C: must have platelet count of less than 75,000 and currently be on treatment with or anticipating hepatitis C treatment with interferon product. For aplastic anemia: must have severe disease, must have platelet count less than 30,000, and must have previous inadequate response or intolerance to antithymocyte globulin-based immunosuppressive therapy (Atgam, Thymoglobulin). For reauth: must have documentation from prescriber indicating improvement in condition (all dx), improvement in platelet count from baseline (all dx), and hematologic response (aplastic anemia dx: increase in platelet count, increase in Hgb, increase in ANC, reduction in frequency of platelet or RBC transfusions). In addition, eltrombopag tx should be discontinued for any of the following: if platelet count does not increase to sufficient level to avoid clinically important bleeding after 4 weeks of tx max daily dose of 75mg (ITP dx only) or 150mg (aplastic anemia dx only), if ALT levels increase to greater than or equal to 3x upper limit of normal and are any of the following (progressive, persistant for at least 4 weeks, accompanied by increased direct bilirubin, accompanied by clinical symptoms of liver injury or evidence of hepatic decompensation), if platelet count is greater than 400,000 after 2 weeks of therapy at lowest eltrombopag dose, when antiretroviral therapy is discontinued (Hep C dx only).
Age Restrictions	ITP: age 1 year or older. Other diagnoses: age 18 years or older.
Prescriber Restrictions	ITP, aplastic anemia: hematologist or oncologist. Hep C: gastroenterologist, hematologist, or hepatologist.
Coverage Duration	90 days
Other Criteria	Not Applicable

PULMOZYME

Products Affected

- Pulmozyme

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of cystic fibrosis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Pulmonologist
Coverage Duration	365 Days
Other Criteria	Not Applicable

PURIXAN

Products Affected

- Purixan

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have a trial and failure of mercaptopurine tablets or have chart documentation of the clinical rationale for why the tablet version cannot be used.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a hematologist or an oncologist
Coverage Duration	365 days
Other Criteria	Not Applicable

QUETIAPINE

Products Affected

- quetiapine oral tablet 100 mg, 200 mg, 25 mg, 300 mg, 400 mg, 50 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

QUININE

Products Affected

- quinine sulfate

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of malaria. For reauth: must have documentation from prescriber indicating continued benefit from therapy.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 Days
Other Criteria	Not Applicable

RAGWITEK

Products Affected

- Ragwitek

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	History of any severe systemic allergic reaction. History of eosinophilic esophagitis. Severe, unstable or uncontrolled asthma. On concomitant immunotherapy.
Required Medical Information	Diagnosis. Must have moderate to severe short ragweed pollen-induced allergic rhinitis with or without conjunctivitis. Must have diagnosis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen and chart documentation demonstrating seasonal symptoms to ragweed-pollen from the previous pollen season. Must have chart documentation demonstrating daily concomitant use of an inhaled nasal corticosteroid (i.e. fluticasone) and an oral antihistamine (i.e. levocetirizine) during the previous pollen season with inadequate responses or significant side effects/toxicities or have contraindication to these therapies. Must have plan for first dose to be administered in physician office due to potential for life threatening allergic reactions, including anaphylaxis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Allergist or immunologist
Coverage Duration	180 days
Other Criteria	Therapy must be initiated 12 weeks prior to the onset of short ragweed pollen season.

RAVICTI

Products Affected

- Ravicti

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation describing how diagnosis was confirmed (e.g. genetic testing results, enzyme assays, ammonia levels, progress notes, etc.). Must have chart documentation of an adequate trial of sodium phenylbutyrate with either inadequate response despite dose titration or significant side effect/toxicity or have a contraindication to this therapy. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with physician who specializes in the treatment of inherited metabolic disorders.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

REGRANEX

Products Affected

- Regranex

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Neoplasm at site of application
Required Medical Information	Diagnosis. For treatment of diabetic neuropathic ulcers, patient must have a lower extremity diabetic neuropathic ulcer. Treatment will be given in combination with ulcer wound care (i.e. debridement, infection control, and/or pressure relief). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	20 weeks
Other Criteria	Not Applicable

RELISTOR

Products Affected

- Relistor subcutaneous solution
- Relistor subcutaneous syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For opioid-induced constipation and advanced life-limiting illness: must have documentation of previous trial of lactulose. For opioid-induced constipation with chronic non-cancer pain: must have documentation of current and ongoing opioid therapy and must have adequate trials of 2 of the following with inadequate responses or significant side effects/toxicity or have a contraindication to these therapies: naloxegol (Movantik), lubiprostone (Amitiza), or lactulose. For reauth: must have documentation from prescriber indicating improvement in condition (both diagnoses) and must continue to be on opioid therapy (non-cancer pain).
Age Restrictions	Age 18 years or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Initial: 90 days (non-cancer pain), 120 days (life-limiting illness). Reauth: 365 days.
Other Criteria	Not Applicable

RELISTOR TABLET

Products Affected

- Relistor oral

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have documentation of current and ongoing opioid therapy and must have adequate trials of naloxegol (Movantik) and lubiprostone (Amitiza) with inadequate responses or significant side effects/toxicity or have a contraindication to these therapies. For reauth: must have documentation from prescriber indicating improvement in condition (both diagnoses) and must continue to be on opioid therapy.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Initial: 90 days Reauth: 365 days.
Other Criteria	Not Applicable

REMICADE

Products Affected

- Remicade

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with infliximab.
Required Medical Information	Diagnosis. Current patient weight (within the last 3 months), dosage and frequency of infusions. Negative TB skin test. For plaque psoriasis: must have chronic moderate to severe disease. For ankylosing spondylitis: must have active disease. For all other dx: must have moderately to severely active disease. For RA: adequate trial of methotrexate with inadeq response (if significant side effects/toxicity or contraindication to methotrexate must have adequate trial of hydroxychloroquine, leflunomide, or sulfasalazine). For psoriatic arthritis (peripheral disease): must have an adequate trial of 1 NSAID at target anti-inflammatory dose and of 1 conventional systemic therapy (e.g. methotrexate, cyclosporine, leflunomide, sulfasalazine) with inadeq responses or significant side effects/toxicities unless contraindicated. For psoriatic arthritis (axial, skin, nail, enthesitis, or dactylitis dominant): must have an adequate trial of 2 NSAIDs at target anti-inflammatory dose with inadeq response or sig. side effects/toxicities unless contraindicated. For ankylosing spondylitis: adequate trial of 2 NSAIDs at target anti-inflammatory dose with inadeq response or significant side effects/toxicity or have a contraindication. For plaque psoriasis: minimum BSA involvement of at least 5% (not required if on palms, soles, head/neck, genitalia), adequate trial of 1 topical treatment or phototherapy or photochemotherapy with inadeq response or significant side effects/toxicity unless contraindicated, and adequate trial of 1 conventional systemic therapy (e.g. methotrexate, acitretin, cyclosporine) with inadeq response or significant side effects/toxicity unless contraindicated. For Crohn's, UC: adequate trial of 1 conventional therapy incl corticosteroid, 5-ASA agent (UC only), or immunosuppressant with inadeq response or significant side effects/toxicity unless contraindicated. For reauth: documentation from prescriber indicating improvement in condition.
Age Restrictions	Crohn's, UC: age 6 years or older. Other dx: age 18 years and older
Prescriber Restrictions	RA, ankylosing spondylitis: rheumatologist. Psoriatic arthritis: rheumatologist, dermatologist. Plaque psoriasis: dermatologist. Crohn's, UC: gastroenterologist.

PA Criteria	Criteria Details
Coverage Duration	365 days
Other Criteria	Dose and frequency of infusions should be in accordance with the FDA label. When doses are requested in excess of established FDA parameters, they will be subject to review for medical necessity.

REMODULIN

Products Affected

- Remodulin

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of PAH (WHO Group I) confirmed diagnosis by right heart catheterization. Must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than or equal to 25 mmHg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than 3 Wood units. Must have WHO Functional Class II-IV symptoms. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Pulmonary hypertension specialist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

REPATHA

Products Affected

- Repatha Pushtronex
- Repatha SureClick
- Repatha Syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have confirmed diagnosis of heterozygous familial hypercholesterolemia, homozygous familial hypercholesterolemia (HoFH, see Other Criteria section) or clinical atherosclerotic cardiovascular disease (ASCVD, see Other Criteria section). Must have baseline and target LDL-cholesterol levels. Must have LDL-C level above target despite adequate trial of 2 high intensity statins (atorvastatin 40-80mg daily and rosuvastatin 20-40mg daily), unless intolerant to statin treatment (defined as confirmed, intolerable statin-related adverse effects or biomarker abnormalities that improve or resolve with statin dose decrease or discontinuation) or statin treatment is contraindicated (defined as documented active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels). If able to tolerate statin, must continue treatment with statin at maximally tolerated dose. For reauth: must have documentation of: (1) recent assessment of LDL-C level with decrease and (2) continued treatment with maximally tolerated dose of a statin (if applicable).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a cardiologist or an endocrinologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	HoFH: must be confirmed by genetic testing with functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality or have clinical diagnosis defined as one of the following (1) untreated LDL greater than 500mg/dL AND untreated total cholesterol (TC) greater than 500mg/dL and triglycerides (TG) less than 300mg/dL with both parents with untreated TC greater than 250mg/dL, (2) skin fibroblast LDL receptor activity less than 20% of normal AND untreated TC greater than 500mg/dL and TG less than 300mg/dL with both parents

PA Criteria	Criteria Details
	with untreated TC greater than 250mg/dL, (3) presence of cutaneous and tendon xanthomas and corneal arcus in first decade of life AND untreated TC greater than 500mg/dL and TG less than 300mg/dL with both parents with untreated TC greater than 250mg/dL, (4) untreated LDL greater than 500mg/dL AND skin fibroblast LDL receptor activity less than 20% of normal, (5) untreated LDL greater than 500mg/dL AND presence of cutaneous and tendon xanthomas and corneal arcus in first decade of life.For ASCVD: must have chart documentation confirming history of at least one of the following: myocardial infarction or other acute coronary syndromes (including ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, and unstable angina), coronary or other revascularization procedure, ischemic stroke or transient ischemic attack, atherosclerotic peripheral arterial disease (includes ankle/brachial index of less than 0.90), coronary artery calcium greater than or equal to 300 Agatston units or greater than or equal to 75th percentile for age/sex/ethnicity, carotid plaque greater than or equal to 50%, coronary atherosclerosis as demonstrated by angiography (cardiac CT angiography or conventional cardiac catheterization).

REVLIMID

Products Affected

- Revlimid oral capsule 10 mg, 15 mg, 2.5 mg, 20 mg, 25 mg, 5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

REXULTI

Products Affected

- Rexulti oral tablet 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For Major Depressive Disorder: must have adequate trial and failure or inadequate response or intolerance to aripiprazole and must be on concomitant therapy with an SSRI or SNRI as adjunctive treatment. For Schizophrenia: must have an adequate trial and failure or inadequate response or intolerance to 2 generic oral atypical antipsychotics (e.g. aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

RITUXAN

Products Affected

- Rituxan

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of severe active infection. Use of TNF-blocking or other biologic agent in combination with rituximab. PML or history of PML. Use of rituximab for maintenance therapy for Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA).
Required Medical Information	Diagnosis. For RA: must have moderate to severe RA, must be on concurrent methotrexate therapy, must have adequate trials of etanercept and adalimumab with inadequate responses or significant side effects/toxicities unless contraindicated. For Wegener's Granulomatosis and Microscopic Polyangitis: must be used as induction therapy for remission, must be on concomitant therapy w/ glucocorticoids. For reauth: must have doc from prescriber indicating improvement in condition (RA, cancer).
Age Restrictions	Age 18 years or older
Prescriber Restrictions	RA, Wegeners, Microscopic Polyangitis: rheumatologist. Cancer: hematologist, oncologist.
Coverage Duration	365 days
Other Criteria	This criteria is for non-antineoplastic use only. For the treatment of cancer diagnoses, the medication will be covered under either the Part B or Part D plan in accordance with CMS regulations. For WG and MPA, additional courses will not be authorized.

RUBRACA

Products Affected

- Rubraca

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming BRCA mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

SABRIL

Products Affected

- Sabril

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must undergo vision testing prior to beginning treatment. For Refractory Complex Partial Seizures: must have inadequate response to 2 combination anticonvulsant regimens (at least 1 of the regimens must contain phenytoin or carbamazepine), must be using in combination with at least 1 other anticonvulsant medication. For reauth: must have documentation from prescriber indicating improvement in condition and that member is undergoing vision testing at least every 3 months during treatment with vigabatrin.
Age Restrictions	Seizure: age 10 years or older. Infantile spasms: age 1 month to 2 years.
Prescriber Restrictions	Neurologist or pediatric neurologist.
Coverage Duration	365 days
Other Criteria	For infantile spasms will not be extended beyond the age of 2 years.

SAMSCA

Products Affected

- Samsca oral tablet 15 mg, 30 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Anuria, on concomitant therapy with a strong CYP3A inhibitor, underlying liver disease (including cirrhosis), hypovolemic hyponatremia
Required Medical Information	Diagnosis. Must have serum sodium less than 125mEq/L OR symptomatic hyponatremia that resisted correction with 72 hours of both of the following interventions: (1)fluid restriction of less than 1000mL/day and (2)consideration of discontinuation of agents known to cause SIADH when clinically feasible (e.g. chlorpropamide, selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants, clofibrate, carbamazepine, vincristine, nicotine, narcotics, antipsychotic drugs, ifosfamide, cyclophosphamide, NSAIDs, MDMA, desmopressin, oxytocin, vasopressin). Must have CrCl greater than 10mL/min. Must be initiated and titrated in hospital setting with close serum sodium monitoring. Must be able to sense and appropriately respond to thirst. If SIADH is underlying cause of hyponatremia, must provide chart documentation of clinical work-up to rule out other diagnoses and clinical rationale for diagnosis and exclusion of other diagnoses (must demonstrate all of the following: decreased plasma osmolality of less than 275 mosm/kg, increased urinary osmolality of greater than 100mosm/kg during hypotonicity, urinary sodium greater than 20mmol/L with normal dietary salt intake, clinical euvolemia, normal thyroid and adrenal function, and no recent use of antidiuretics within 24 hours of laboratory testing.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Endocrinologist or nephrologist
Coverage Duration	30 days
Other Criteria	Due to risk of liver injury, tolvaptan should not be administered for more than 30 days.

SANDOSTATIN LAR

Products Affected

- Sandostatin LAR Depot intramuscular suspension,extended rel recon

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For acromegaly: must have inadequate response to surgery or radiation therapy or have documentation that these therapies are inappropriate AND must have confirmed diagnosis with elevated serum IGF-1 for age/gender (must provide lab reference range) and elevated growth hormone level greater than or equal to 1ng/mL during oral glucose tolerance test. For severe diarrhea and flushing episodes: must be associated with metastatic carcinoid tumor. For profuse watery diarrhea: must be associated with vasoactive intestinal peptide secreting tumor. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with an endocrinologist, hematologist, oncologist, gastroenterologist, or palliative care specialist depending upon diagnosis.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

SAPHRIS

Products Affected

- Saphris (black cherry) sublingual tablet 10 mg, 2.5 mg, 5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have tried and failed 2 atypical antipsychotics.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

SAVELLA

Products Affected

- Savella oral tablet
- Savella oral tablets,dose pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation showing history of widespread pain involving the extremities for 3 months and localized areas of tenderness. Must have chart documentation or claims history showing a trial of gabapentin at a dose of at least 1200mg/day with inadequate response or significant side effects/toxicity despite slow dose titration or have a contraindication to this therapy. Must have chart documentation or claims history showing a trial of a tricyclic antidepressant (e.g. amitriptyline) or muscle relaxant (e.g. cyclobenzaprine) with inadequate response or significant side effects/toxicity or have a contraindication to these therapies.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

SEROQUEL XR

Products Affected

- quetiapine oral tablet extended release 24 hr
- Seroquel XR oral tablet extended release 24 hr

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For schizophrenia, bipolar disorder: must have previous trial and failure of immediate-release quetiapine. For major depressive disorder: must have adequate trial and failure (duration at least 4 weeks) with 2 different antidepressant therapies (e.g. SSRIs, SNRIs) with inadequate responses or intolerance.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

SEROSTIM

Products Affected

- Serostim subcutaneous recon soln 4 mg, 5 mg, 6 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have tried and failed 2 other medications used for AIDS wasting (e.g. dronabinol, megesterol, oxandrolone). Must be compliant with anti-retroviral medications. For reauth: must have documentation from prescriber that member has experienced weight stabilization or weight gain.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Initial: 84 days. Reauth: 252 dys. Total treatment not to exceed: 336 dys/yr.
Other Criteria	Not Applicable

SIGNIFOR

Products Affected

- Signifor

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of confirmed pituitary source of Cushing's syndrome. Must previously have had pituitary surgery (e.g. transsphenoidal surgery) that was not curative unless not a candidate for surgery. Must have baseline 24-hour urinary free cortisol level. Must have recent (within 6 months) baseline assessments of fasting plasma glucose, liver function tests, electrocardiogram, gallbladder ultrasound, pituitary hormones (e.g. TSH, free T4, growth hormone, IGF-1), and hemoglobin A1C. Must provide chart documentation of optimized anti-diabetic therapy if baseline hemoglobin A1C is greater than 8%. For reauth: must have documentation from prescriber indicating improvement in condition based on reduction in 24-hour urinary free cortisol level from baseline level as well as signs and symptoms of improvement in the disease (e.g. blood pressure, lipids, weight) and must have documentation that hemoglobin A1C, fasting plasma glucose, liver function tests, gallbladder ultrasound, pituitary hormones, and electrocardiogram have all been reassessed within 3 months of starting pasireotide and at regular intervals thereafter.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with an endocrinologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

SIGNIFOR LAR

Products Affected

- Signifor LAR

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of acromegaly. Must have following baseline labs: elevated serum IGF-1 level for gender/age range (including lab reference range) and elevated growth hormone level (defined as GH at least 1ng/mL during oral glucose tolerance test). Must have inadequate response to surgery or radiation therapy or documentation that these therapies are inappropriate. Must have recent (within 6 months) baseline assessment of hemoglobin A1C. Must provide chart documentation of optimized anti-diabetic therapy if baseline hemoglobin A1C is greater than 8%. Must have a previous trial of octreotide acetate (Sandostatin LAR) or lanreotide (Somatuline Depot) with an inadequate response or intolerance. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with an endocrinologist
Coverage Duration	365 days
Other Criteria	Not Applicable

SILDENAFIL

Products Affected

- Revatio oral suspension for reconstitution
- sildenafil oral

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Current use of nitrate product
Required Medical Information	Diagnosis of PAH (WHO Group I) confirmed diagnosis by right heart catheterization. Must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than or equal to 25 mmHg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than 3 Wood units. Must have WHO Functional Class II-IV symptoms. For sildenafil suspension: must have chart documentation of the clinical rationale for why sildenafil tablet cannot be used. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Cardiologist or pulmonologist. Combination therapy with two or more PAH agents must be prescribed by or in consultation with a pulmonary hypertension specialist.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

SIMPONI

Products Affected

- Simponi subcutaneous pen injector 100 mg/mL, 50 mg/0.5 mL
- Simponi subcutaneous syringe 100 mg/mL, 50 mg/0.5 mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with golimumab.
Required Medical Information	Diagnosis. Negative tuberculosis skin test. For RA, psoriatic arthritis, ankylosing spondylitis: must have adequate trials of etanercept and adalimumab with inadequate responses. For RA: must have moderately to severely active RA, must be on concurrent methotrexate therapy. For psoriatic arthritis: must have moderately to severely active disease. For ankylosing spondylitis: must have active disease. For ulcerative colitis: must have moderate to severe disease, must have an adequate trial of adalimumab with an inadequate response AND adequate trial of 1 conventional therapy (such as a corticosteroid, a 5-ASA agent, or an immunosuppressant) with inadequate response or significant side effects/toxicity unless contraindicated. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	RA, ankylosing spondylitis: rheumatologist. Psoriatic arthritis: rheumatologist, dermatologist. UC: gastroenterologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

SIMPONI ARIA

Products Affected

- Simponi ARIA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with golimumab.
Required Medical Information	Diagnosis. Negative tuberculosis skin test. Must have adequate trials of methotrexate with an inadequate response, must have moderately to severely active RA, must be on concurrent methotrexate therapy. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Rheumatologist
Coverage Duration	365 days
Other Criteria	Not Applicable

SIROLIMUS

Products Affected

- Rapamune oral solution
- sirolimus

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Must have diagnosis of lymphangioleiomyomatosis or prophylaxis of organ rejection. For prophylaxis of organ rejection, must have undergone solid organ transplant and must have at least one of the following: renal dysfunction, coronary allograft vasculopathy following heart transplant, OR trial and failure (defined as intolerance to regimen or inability of regimen to prevent rejection at appropriate therapeutic dosing) of anti-rejection regimen containing at least 2 drugs (including cyclosporine, tacrolimus, azathioprine, mycophenolate mofetil, mycophenolate sodium).
Age Restrictions	Prophylaxis of organ rejection: age 13 years or older. Lymphangioleiomyomatosis: age 18 years or older.
Prescriber Restrictions	Prophylaxis of organ rejection: by or in consultation with a transplant specialist. Lymphangioleiomyomatosis: pulmonologist, hematologist, or oncologist.
Coverage Duration	365 Days
Other Criteria	B vs. D determination will be made prior to clinical criteria being applied.

SIRTURO

Products Affected

- Sirturo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have previously had inadequate response to at least one first-line TB regimen containing isoniazid and rifampin OR have chart documentation of susceptibility testing of Mycobacterium tuberculosis isolates demonstrating resistance to isoniazid and rifampin. Must be using bedaquiline in combination with at least three other drugs active against pulmonary TB. Must provide documentation that the member understands importance of compliance to full medication regimen. For reauth: must have documentation from prescriber indicating member's initial response to therapy and clinical rationale for continuation of treatment or for re-treatment, must have documentation that member was compliant with previous course of therapy, AND must have chart documentation of susceptibility testing of Mycobacterium tuberculosis isolates demonstrating continued susceptibility to bedaquiline.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with an infectious disease specialist or pulmonologist
Coverage Duration	180 days
Other Criteria	Not Applicable

SKELETAL MUSCLE RELAXANTS

Products Affected

- carisoprodol oral tablet 350 mg
- carisoprodol-ASA-codeine
- carisoprodol-aspirin
- chlorzoxazone
- cyclobenzaprine oral tablet 10 mg, 5 mg
- methocarbamol oral
- orphenadrine citrate injection
- orphenadrine citrate oral

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have attestation from prescriber assessing the risks and benefits of therapy and desire to prescribe a muscle relaxant.
Age Restrictions	Age 65 years or older: criteria apply. Age less than 65 years: criteria do not apply.
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

SODIUM PHENYLBUTYRATE

Products Affected

- Buphenyl oral tablet
- sodium phenylbutyrate

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation describing how diagnosis was confirmed (e.g. genetic testing results, enzyme assays, ammonia levels, progress notes, etc.). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a hematologist, nephrologist, or physician who specializes in the treatment of inherited metabolic disorders.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

SOMATULINE DEPOT

Products Affected

- Somatuline Depot subcutaneous syringe 120 mg/0.5 mL, 60 mg/0.2 mL, 90 mg/0.3 mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For acromegaly: must have baseline labs (elevated serum IGF-1 level for gender/age range, including lab reference range, and elevated growth hormone level defined as GH at least 1ng/mL during oral glucose tolerance test), must have inadequate response to surgery or radation therapy or documentation that these therapies are inappropriate. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Acromegaly: by or in consultation with an endocrinologist. GEP-NETs: by or in consultation with a hematologist, an oncologist, an endocrinologist, or a palliative care specialist.
Coverage Duration	365 days
Other Criteria	Not Applicable

SOMAVERT

Products Affected

- Somavert

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of acromegaly. Must have following baseline labs: elevated serum IGF-1 level for gender/age range (including lab reference range) and elevated growth hormone level defined as GH at least 1ng/mL during oral glucose tolerance test. Must have inadequate response to surgery or radation therapy or documentation that these therapies are inappropriate. Must have inadequate response to 1 medical therapy (e.g. octreotide, octreotide LAR, lanreotide) or documenation that these therapies are inappropriate. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with an endocrinologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

SOVALDI

Products Affected

- Sovaldi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D and chronic Hepatitis C genotypes 5 and 6
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of chronic Hep C. Doc of prior treatment (tx) for Hep C and response to that tx. Non-responder: fail to clear virus after 24 wks of tx w/ interferon(IFN)/ribavirin(RBV). Null responder: less than 2-log10 decrease in virus at week 12 of prior tx w/ IFN/RBV. Partial responder: greater than/equal to 2-log10 decrease in virus at week 12 but no sustained virological response (no virus 24 weeks after tx d/c'd) w/ prior tx w/ IFN/RBV. Relapser: initial response to tx (complete elimination of virus) but virus returns after meds discontinued. Chart doc of lab genotype(GT) result, detectable baseline HCV RNA level (incl. assay date, ref. range), test indicating presence or absence of cirrhosis (e.g. F4 score on liver biopsy from within past 3 years, MRI, ultrasound, CT scan). GT 2 and 3 pts, IFN ineligible: chart doc of clinical rationale and 1 of following: decompensated cirrhosis w/ Child-Pugh greater than 6, platelet count less than 90,000/mm3, ANC less than 1500/mm3, SrCr greater than 1.5xULN, CD4+ count less than 100/mm3 w/ HIV co-infection, hemoglobin less than 10g/dL, retinopathy, autoimmune disease, severe uncontrolled psych disease classified by chart doc of eval by behavioral health specialist, history of pre-existing unstable heart disease, side effects to prior IFN tx leading to d/c. Hep C w/ hepatocellular carcinoma awaiting liver txfr: must be awaiting liver txfr currently and have chart doc of hepatocellular carcinoma meeting Milan criteria (no extrahepatic cancer manifestations cancer or evidence of vascular invasion of tumor AND tumor 5cm or less in diameter when single hepatocellular carcinoma or no more than 3 tumor nodules each 3cm or less in diameter when multiple tumors), for reauth must still be awaiting liver txfr. Decompensated cirrhosis: Child-Pugh Score greater than 6. For GT 1: must have clinical rationale describing why Harvoni cannot be used.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Infectious disease physician, gastroenterologist, hepatologist, HIV specialist, or transplant physician

PA Criteria	Criteria Details
Coverage Duration	12 wks, 16 wks, 24 wks, or 48 wks based upon GT and regimen
Other Criteria	Regimens/requirements based on AASLD/IDSA Hep C Tx Guidelines. Sofosbuvir (SOF), Ribavirin (RBV), Interferon (IFN).GT 1 AND unable to use Harvoni: approve x12 wks or x24 weeks (based upon regimen used). GT 2, tx naive: use SOF/RBV (approve x12 wks, or x16 wks if cirrhosis). GT 2, treatment-experienced w/ IFN/RBV: use SOF/RBV (approve x16 or x24 weeks) OR use SOF/IFN/RBV (approve x12 wks). GT 2, treatment-experienced with SOF/RBV: use SOF/IFN/RBV (approve x12 weeks). GT 3, tx naive, non-cirrhotic: use SOF/IFN/RBV (approve x12 wks), OR if IFN ineligible use SOF/RBV (approve x24 wks). GT 3, tx naive, cirrhotic: use SOF/IFN/RBV (approve x12 wks), OR if IFN ineligible use SOF/RBV (approve x24 wks) . GT 3, treatment-experienced w/ SOF/RBV: use SOF/IFN/RBV (approve x12 weeks). GT 3, treatment-experienced w/ IFN/RBV, non-cirrhotic: use SOF/IFN/RBV (approve x12 wks). GT 3, treatment experienced w/ IFN/RBV, cirrhotic: use SOF/IFN/RBV (approve x12 wks). GT 4: use SOF/RBV (approve x24 weeks) OR SOF/IFN/RBV (approve x12 weeks). GT 5, 6: use SOF/IFN/RBV (approve x12 wks). Hep C w/ HIV co-infection: regimen based upon GT. GT 2 or 3 w/ decompensated cirrhosis: use SOF/RBV (approve x48 wks). GT 2 post liver txfr, able to use RBV: use SOF/RBV (approve x24 wks). GT 3 post liver txfr, decompensated cirrhosis: use SOF/RBV (approve x24 wks). GT 3 liver txfr, no decompensated cirrhosis, able to use RBV: approve SOF/RBV (approve x24 wks). Hep C w/ hepatocellular carcinoma awaiting liver txfr: use SOF/RBV (approve x12 wks initial, reauth x12 wks if still awaiting txfr, up to 48 weeks or time of liver txfr, whichever comes 1st).

SPRITAM

Products Affected

- Spritam

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have had an inadequate response or intolerance to generic levetiracetam and one other generic antiepileptic drug (such as carbamazepine, oxcarbazepine, or phenytoin) and be using levetiracetam (Spritam) as adjunctive therapy to other antiepileptic drugs (which can include medications from trials above).
Age Restrictions	Age 4 years or older
Prescriber Restrictions	By or in consultation with a neurologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

SPRYCEL

Products Affected

- Sprycel oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

STELARA

Products Affected

- Stelara intravenous
- Stelara subcutaneous syringe 45 mg/0.5 mL, 90 mg/mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with ustekinumab.
Required Medical Information	Diagnosis. Negative TB skin test. Must provide patient weight. For plaque psoriasis: must have moderate to severe plaque psoriasis, must have minimum body surface area of at least 5% (not required if on palms, soles, head/neck, or genitalia), must have adequate trial of 1 conventional systemic therapy (e.g. methotrexate, acitretin, cyclosporine) with inadequate response or significant side effects/toxicity unless contraindicated, and must have adequate trial of 1 topical treatment, phototherapy, or photochemotherapy with inadequate response or significant side effects/toxicity unless contraindicated. For psoriatic arthritis (peripheral disease): must have active disease, must have adequate trial of one NSAID at anti-inflammatory target dose and of one conventional systemic therapy (e.g. methotrexate, cyclosporine, sulfasalazine, or leflunomide) with inadequate responses or significant side effects/toxicity unless contraindicated. For psoriatic arthritis (axial, skin, nail, enthesitis, or dactylitis dominant): must have an adequate trial of 2 NSAIDs at target anti-inflammatory dose with inadeq response or sig. side effects/toxicities unless contraindicated. For Crohns: must have moderately to severely active disease, must have adequate trial of 1 conventional therapy (e.g., corticosteroids, immunomodulators) with inadequate response or significant side effects/toxicities unless contraindicated. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Psoriasis: dermatologist. Psoriatic arthritis: rheumatologist or dermatologist. Crohns: gastroenterologist.
Coverage Duration	365 days
Other Criteria	Must follow recommended dosing guidelines based upon weight.

STIMULANTS

Products Affected

- dexmethylphenidate oral tablet
- dextroamphetamine oral capsule, extended release 10 mg, 15 mg, 5 mg
- dextroamphetamine oral tablet
- dextroamphetamine-amphetamine oral capsule,extended release 24hr 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 5 mg
- dextroamphetamine-amphetamine oral tablet 10 mg, 12.5 mg, 15 mg, 20 mg, 30 mg, 5 mg, 7.5 mg
- Metadate ER
- methylphenidate oral capsule, ER biphasic 30-70
- methylphenidate oral capsule,ER biphasic 50-50 20 mg, 40 mg, 60 mg
- methylphenidate oral solution 10 mg/5 mL, 5 mg/5 mL
- methylphenidate oral tablet 10 mg, 20 mg, 5 mg
- methylphenidate oral tablet extended release
- methylphenidate oral tablet extended release 24hr 18 mg, 27 mg, 36 mg, 54 mg
- Zenzedi oral tablet 10 mg, 5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For ADHD: must have chart documentation of ADHD screening if new start. For narcolepsy: must have chart documentation of sleep study confirming diagnosis. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older: criteria apply. Age less than 18 years: criteria do not apply.
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

STIVARGA

Products Affected

- Stivarga

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. ECOG Performance Status.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

STRENSIQ

Products Affected

- Strensiq

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have an onset of symptoms prior to age 18. Reauth: must have chart documentation of improvement in the member's condition, including skeletal manifestations.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with an endocrinologist, geneticist, or metabolic disorders specialist
Coverage Duration	Initial: 180 days. Reauth: 365 days
Other Criteria	Not Applicable

SUBOXONE AND SUBUTEX

Products Affected

- buprenorphine HCl sublingual
- Suboxone
- Zubsolv sublingual tablet 1.4-0.36 mg, 11.4-2.9 mg, 2.9-0.71 mg, 5.7-1.4 mg, 8.6-2.1 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For buprenorphine-only product: member must have documentation of intolerance to naloxone or female member must be pregnant. For initial auth: must have chart documentation of urine drug screen (UDS) within last 3 months consistent with dx of opioid dependence. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Initial: 90 days. Reauth: 180 days.
Other Criteria	Not Applicable

SUCRAID

Products Affected

- Sucraid

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For congenital sucrase-isomaltase deficiency: must have low sucrase activity on duodenal biopsy with other disaccharidases normal on same duodenal biopsy OR must have stool pH less than 6, increase in breath hydrogen of greater than 10ppm when challenged with sucrose after fasting, and negative lactose breath test. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 5 months or older
Prescriber Restrictions	Gastroenterologist, endocrinologist, or metabolic specialist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

SUTENT

Products Affected

- Sutent oral capsule 12.5 mg, 25 mg, 37.5 mg, 50 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

SYLVANT

Products Affected

- Sylvant intravenous recon soln 100 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. HIV or HHV 8 positive
Required Medical Information	Diagnosis. Must have chart documentation demonstrating a history of (1)lymphadenopathy in greater than one lymph node site and (2)constitutional symptoms such as fever, night sweats, significant weight loss, fatigue, weakness, anorexia, anemia.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

SYNAGIS

Products Affected

- Synagis intramuscular solution 50 mg/0.5 mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. If under age 12 mo at start of RSV season w/ no other medical dx: must have gestational age (GA) less than 29 wks. If under age 24 mo at start of RSV season during 1st year of life w/ Chronic Lung Disease (CLD) of prematurity: must have GA less than 32 weeks 0 days AND required greater than 21% oxygen (O2) for at least first 28 days of life. If under age 24 mo at start of RSV season during 2nd year of life w/ CLD of prematurity: must have GA less than 32 weeks 0 days AND required greater than 21% O2 for at least first 28 days of life AND have continued to require medical support (chronic corticosteroid therapy, diuretic therapy, supplemental O2) during 6 months before start of 2nd RSV season. If under age 12 mo at start of RSV season w/ heart disease: must have hemodynamically significant Congenital Heart Disease (CHD) (and be on drugs to control heart failure) OR have acyanotic heart disease (and be on drugs to control heart failure and require cardiac surgery) OR have mod-sev pulm HTN OR have cardiac lesions adequately corrected by surgery (and still continue to be on drugs for heart failure). If under age 12 mo at start of RSV season w/ neuromuscular disease or congenital anomaly: must demonstrate that disease/anomaly impairs ability to clear secretions from upper airway b/c of ineffective cough. If under age 24 mo at start of RSV season and profoundly immunocompromised: must have doc of reason (e.g. severe combined immunodeficiency, severe T-cell deficiency, severe AIDS, AML, acute lymphoblastic leukemia, receiving chemotx, received hematopoietic SCT). If under age 24 mo w/ cystic fibrosis (CF): during 1st year of life must have clinical evidence of CLD and/or nutritional compromise OR during 2nd year of life must have manifestation of severe lung disease (prior hospitalization for pulmonary exacerbation in 1st year of life, abnormalities on chest radiography/CT that persist when stable, weight for length is less than 10th %.
Age Restrictions	Less than 12 months or less than 24 months of age at start of RSV season depending on criteria
Prescriber Restrictions	No Prescriber Restrictions

PA Criteria	Criteria Details
Coverage Duration	Maximum of 5 doses per RSV season.
Other Criteria	Not Applicable

SYPRINE

Products Affected

- Syprine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of how diagnosis was confirmed including at least one of the following: hepatic parenchymal copper content greater than or equal to 250 micrograms per gram dry weight, presence of Kayser-Fleischer Ring in cornea, serum ceruloplasmin level less than 50mg/L, basal 24-hour urinary excretion of copper greater than 100 micrograms (1.6 millimoles), or genetic testing indicating mutation in ATP7B gene. Must have adequate trial of penicillamine (Depen) with an inadequate response or significant side effects/toxicity or must have a contraindication to this therapy. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a gastroenterologist, ophthalmologist, or physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration	Initial: 90 days. Reauth 365 days.
Other Criteria	Not Applicable

TABLOID

Products Affected

- Tabloid

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

TAFINLAR

Products Affected

- Tafinlar oral capsule 50 mg, 75 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming BRAFV600E or BRAFV600K mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

TAGRISSO

Products Affected

- Tagrisso oral tablet 40 mg, 80 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming epidermal growth factor receptor (EGFR) T790M mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

TALTZ

Products Affected

- Taltz Autoinjector (3 Pack)
- Taltz Syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of TNF-blocking or other biologic agent in combination with ixekizumab.
Required Medical Information	Diagnosis. Negative TB skin test. Must have chronic moderate to severe plaque psoriasis, with minimum BSA involvement of at least 5% (not required if plaque psoriasis on palms, soles, head, neck, or genitalia). Must have adequate trial of adalimumab and etanercept with an inadequate response or significant side effects/toxicity, or have a contraindication to these therapies. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Dermatologist
Coverage Duration	365 days
Other Criteria	Not Applicable

TARCEVA

Products Affected

- Tarceva oral tablet 100 mg, 150 mg, 25 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For 1st-line treatment of patients w/ metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 substitution mutations: must have chart documentation of laboratory result confirming EGFR mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

TARGRETIN

Products Affected

- bexarotene

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

TASIGNA

Products Affected

- Tasigna oral capsule 150 mg, 200 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

TCA

Products Affected

- amitriptyline
- clomipramine
- doxepin oral
- imipramine HCl
- imipramine pamoate
- trimipramine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D and urticaria for doxepin
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Approve amitriptyline, doxepin (doses higher than 6mg/day), imipramine, or trimipramine if prior trial and failure of 2 of following for depression: SSRIs, venlafaxine, venlafaxine ER capsules, nortriptyline, desipramine, trazodone, mirtazapine, bupropion. Approve clomipramine if prior trial and failure of 2 of following for obsessive-complusive disorder: citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine, venlafaxine ER capsules. Approve doxepin for urticaria if prior trial and failure of levocetirizine. For all other FDA-approved indications, no prior drug trials are required.
Age Restrictions	Age 65 years or older: criteria apply. Age less than 65 years: criteria do not apply.
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

TECFIDERA

Products Affected

- Tecfidera oral capsule,delayed release(DR/EC) 120 mg, 120 mg (14)- 240 mg (46), 240 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of anti-neoplastic, immunosuppressive, or immune-modulating therapies in combination with dimethyl fumarate.
Required Medical Information	Diagnosis. For reauth: must have documentation from prescriber indicating stabilization or improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

TETRABENAZINE

Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Actively suicidal. Uncontrolled depression. Currently using a monoamine oxidase inhibitor or reserpine. Hepatic impairment.
Required Medical Information	Diagnosis. Must have confirmed Huntington's disease either by Huntington Disease Mutation analysis (with laboratory result indicating expanded CAG repeat of greater than or equal to 36 in the huntington gene) or a positive family history of Huntington's Disease with autosomal dominant inheritance pattern. Must have clinical signs of Huntington's Disease to include chart documentatin of a clinical work-up showing one or more of the following signs: motor (e.g. finger tapping, rigidity), oculomotor, bulbar (e.g. dysarthria, dysphagia), affective (e.g. depression), cognitive. Must have chart documentation of chorea associated with Huntington's Disease. For doses greater than 50mg/day: must have chart documentation of an adequate trial of 50mg/day dose with inadequate response OR must be CYP2D6 intermediate or extensive metabolizer (as documented through CYP2D6 genotyping results), must provide documentation of slow dose titration with close monitoring of side effects. For reauth: must have documentation from the prescriber indicating improvement in condition and showing monitoring for depression and suicidal ideation. For reauth for doses greater than 50mg/day: must have chart documentation from prescriber showing inadequate efficacy of lower doses and slow titration of dose with close monitoring of side effects.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	365 days
Other Criteria	Maximum dose approved is 100mg/day.

THALOMID

Products Affected

- Thalomid oral capsule 100 mg, 150 mg, 200 mg, 50 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

THIOLA

Products Affected

- Thiola

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have severe homozygous cystinuria with urinary cystine level greater than 500mg/day. Must have chart documentation of how diagnosis was confirmed. Must have baseline (within 6 months) urinalysis, complete blood cell count, platelet count, hemoglobin, and liver function tests. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a urologist or physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

TRACLEER

Products Affected

- Tracleer

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Current use of glyburide or cyclosporine
Required Medical Information	Diagnosis of PAH (WHO Group I) confirmed diagnosis by right heart catheterization. Must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than or equal to 25 mmHg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than 3 Wood units. Must have WHO Functional Class II-IV symptoms. For patients with WHO Functional Class II and III symptoms: must have previous inadequate response or intolerance to ambrisentan (Letairis). Must have baseline liver function tests (AST, ALT), prior to initiation of therapy. Must have baseline negative pregnancy test prior to initiation of therapy if a female of child-bearing potential. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Cardiologist or pulmonologist. Combination therapy with two or more PAH agents must be prescribed by or in consultation with a pulmonary hypertension specialist.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

TYKERB

Products Affected

- Tykerb

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. ECOG Performance Status.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

TYSABRI

Products Affected

- Tysabri

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Current or history of progressive multifocal leukoencephalopathy (PML). Use of chronic immunosuppressant or immunomodulatory therapy (e.g. 6-mercaptopurine, cyclosporine, methotrexate, TNF-inhibitors) or systemic medical conditions resulting in significant compromised immune function.
Required Medical Information	Diagnosis. For MS: must have relapsing form, must have adequate trial with one other medication used to treat MS such as an interferon beta product (e.g. Avonex or Plegridy), glatiramer, or dimethyl fumarate with an inadequate response or intolerance unless contraindicated. Prior treatment with another MS therapy not required if: rapidly evolving severe relapsing-remitting MS (2 or more disabling relapses in 1 year AND 1 or more gadolinium enhancing lesions on brain MRI or significant increase in T2 lesion load as compared to previous recent MRI) OR presence of 3 or more predictive factors for poor prognosis (age of onset 40 years or older, motor system involvement at onset including weakness of extremities or ataxia, 4 or more T2-weighted lesions suggestive of MS seen on MRI, 2.5 years or less between 1st 2 relapses, 2 or more relapses in 1st year of disease, poor recovery from initial 2 relapses defined as EDSS of 1.5 or higher sustained for at least 1 year). For Crohn's: must have moderately to severely active disease with evidence of inflammation, must have adequate trial of 1 conventional therapy (e.g. aminosalicylates, corticosteroids, immunomodulators) AND adalimumab with inadequate responses or intolerance unless contraindicated. For reauth: must have documentation from prescriber indicating stabilization or improvement in condition, must have weaned off oral corticosteroids within 6 months of starting natalizumab (for Crohn's only).
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Neurologist (for MS) or gastroenterologist (Crohn's) who is registered with the TOUCH Prescribing program.
Coverage Duration	Crohns initial: 90 dys if not on, 180 dys if on chronic oral steroids. Crohns reauth, MS: 365 dys.
Other Criteria	Not Applicable

UCERIS

Products Affected

- Uceris

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection
Required Medical Information	Diagnosis. Must have active mild to moderate ulcerative colitis and be using to induce remission of active disease, AND must have an adequate trial of oral sulfasalazine, oral balsalazide, or oral corticosteroid with an inadequate response or significant side effect/toxicity or have a contraindication to these therapies. Reauth: must have either clinical rationale from prescriber for continuation of treatment beyond 8 weeks OR documentation that member is experiencing a subsequent flare-up and experienced improvement in the condition as a result of treatment with budesonide ER tablet during a previous flare-up.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with a gastroenterologist
Coverage Duration	8 weeks
Other Criteria	Not Applicable

UCERIS FOAM

Products Affected

- Uceris

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection
Required Medical Information	Diagnosis. Must have active mild to moderate distal ulcerative colitis and be using to induce remission of active disease, AND must have an adequate trial of topical mesalamine or topical steroids [e.g. hydrocortisone rectal foam (Cortifoam)] with an inadequate response or significant side effect/toxicity or have a contraindication to these therapies. Reauth: must have either clinical rationale from prescriber for continuation of treatment beyond 6 weeks OR documentation that member is experiencing a subsequent flare-up and experienced improvement in the condition as a result of treatment with budesonide foam during a previous flare-up.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with a gastroenterologist
Coverage Duration	6 weeks
Other Criteria	Not Applicable

UPTRAVI

Products Affected

- Uptravi oral tablet
- Uptravi oral tablets,dose pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of PAH (WHO Group I) confirmed diagnosis by right heart catheterization. Must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than or equal to 25 mmHg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than 3 Wood units. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Cardiologist or pulmonologist. Combination therapy with two or more PAH agents must be prescribed by or in consultation with a pulmonary hypertension specialist.
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

VALCHLOR

Products Affected

- Valchlor

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

VECAMYL

Products Affected

- Vecamyl

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Mild, moderate, and/or labile hypertension. Coronary insufficiency or recent myocardial infarction. Renal insufficiency manifested by rising or elevated BUN level. Uremia. Concurrent use of antibiotics and sulfonamides. Glaucoma. Organic pyloric stenosis. Hypersensitivity to mecamylamine.
Required Medical Information	Diagnosis of moderately severe to severe essential hypertension or uncomplicated malignant hypertension. Must have documented adequate trials of 2 formulary antihypertensive medications that represent 2 different classes of antihypertensive medications such as an angiotensin receptor blocker (i.e. irbesartan) and a thiazide diuretic (i.e. hydrochlorothiazide) with therapeutic failure.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Cardiologist
Coverage Duration	365 days
Other Criteria	Not Applicable

VELTASSA

Products Affected

- Veltassa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have documentation of elevated serum potassium and of target serum potasium level. Must have tried modification of medication regimen to reduce the risk of hyperkalemia if clinically appropriate. Must have trial of, contraindication to, or intolerance to sodium polystyrene sulfonate. For reauth: must have documentation of persistent hyperkalemia and prior reduction in serum potaassium levels with Veltassa (patiromer).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

VEMLIDY

Products Affected

- Vemlidy

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Hepatitis B Virus Drug Resistance panel showing resistance to prior tx w/ tenofovir
Required Medical Information	Diagnosis. Must have documentation of results of Hep B Virus Drug Resistance panel if previously received antiviral tx regimen for Hep B. Must have documentation of baseline eval and results for following tests: Hep B viral (HBV) DNA load, hepatitis B e antigen (HBeAg), antibody to hepatitis B e antigen (anti-HBe), hepatitis B surface antigen (HBsAg), antibody to hepatitis surface antigen (anti-HBs), liver biopsy (if available), alanine aminotransferase (ALT) level and assay reference range. For reauth: must have doc from prescriber indicating continued benefit from tx, doc of recent HBV DNA level, chart doc of HBV Drug Resistance panel if mbr has evidence or virologic breakthrough (greater than 10-fold increase in serum HBV DNA from nadir during tx in mbr who had initial virologic response), and doc of HBeAg/Anti-HBe/HBsAg/Anti-HBs (for mbrs with HBeAg positive and for mbrs with HBeAg negative not falling under any other indications).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Infectious disease physician, gastroenterologist, hepatologist, or transplant physician
Coverage Duration	Pregnant mbr: 6 months. All others: 365 days until disease progression or clearance.
Other Criteria	Regimens/requirements based upon AASLD Practice Guidelines for Chronic Hepatitis B. For HBeAg+ chronic HBV: must meet 1 ALT criterion (ALT greater than or equal to 2xULN OR evidence of moderate/severe inflammation or signif. fibrosis on biopsy) and have HBV DNA level greater than 20,000 IU/mL. For HBeAg- chronic HBV: must meet 1 ALT criterion (ALT greater than or equal to 2xULN, ALT greater than 1xULN w/ evidence of moderate/severe inflammation or signif. fibrosis on biopsy, ALT less than or equal to ULN w/ ALT increased over time) and 1 HBV DNA criterion (HBV DNA greater than 20,000 IU/mL, HBV DNA greater than 2,000 IU/mL w/ evidence of moderate/severe inflammation or signif. fibrosis on biopsy, HBV DNA

PA Criteria	Criteria Details
	less than or equal to 2,000 IU/mL w/ HBV DNA increased over time). For cirrhosis w/ HBV: must have HBV DNA greater than 2,000 IU/mL OR detectable HBV DNA level w/ elevated ALT. For HBV mbr who had liver txfr for HBV or who received solid organ txfr from HBV+ donor: approve regardless of HBV DNA and ALT levels. For HBV carrier who needs immunosuppressive or cytotoxic tx: must be HBsAg+, have planned course of cancer chemotx or immunosuppressive tx. For HBV in mbr currently pregnant to reduce risk of vertical HBV transmission: must be in 3rd trimester of pregnancy and have serum HBV DNA level greater than 10 to the 8th IU/mL. Reauth for HBeAg+: approve x1 year until all of following are met (loss of HBeAg, undetectable serum HBV DNA, completed 6-12 months of additional tx after appearance of anti-HBe). Reauth for HBeAg-: approve x1 yr until loss of HBsAg. Reauth for cirrhosis, for liver txfr for HBV, or for solid organ txfr from HBV+ donor: long-term tx approvable. Reauth for pregnancy: no reauth provided for same pregnancy. Reauth for HBV carriers receiving immunosuppressive or cytotoxic tx: mbr w/ baseline HBV DNA less than 2,000 IU/mL should continue x6 months after completion of chemotx or immunosuppressive tx, mbr w/ baseline HBV DNA greater than 2,000 IU/mL should continue until reach therapeutic endpoints for immunocompetant HBV as listed above.

VENCLEXTA

Products Affected

- Venclexta oral tablet 10 mg, 100 mg, 50 mg
- Venclexta Starting Pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Members who are on concomitant strong CYP3A4 inhibitors during initiation of therapy.
Required Medical Information	Diagnosis. For chronic lymphocytic leukemia with 17p deletion: must have chart documentation of lab result confirming mutation and trial of at least one prior therapy.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

VENTAVIS

Products Affected

- Ventavis

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of PAH (WHO Group I) confirmed diagnosis by right heart catheterization. Must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than or equal to 25 mmHg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than 3 Wood units. Must have WHO Functional Class III-IV symptoms. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Pulmonary hypertension specialist, cardiologist, or pulmonologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	B vs. D determination will be made prior to clinical criteria being applied.

VERSACLOZ

Products Affected

- Versacloz

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have an adequate trial and failure of both clozapine tablet AND clozapine orally-disintegrating tablet or have chart documentation of the clinical rationale for why the tablet and orally-disintegrating tablet versions cannot be used.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

VIBERZI

Products Affected

- Viberzi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Alcoholism, alcohol abuse, or addiction. History of pancreatitis or structural disease of the pancreas. Severe hepatic impairment (Child-Pugh Class C). History of chronic or severe constipation or sequelae from constipation or known or suspected mechanical gastrointestinal obstruction.
Required Medical Information	Diagnosis. For diarrhea-predominant irritable bowel syndrome (IBS-D): must have chart documentation of how the diagnosis was confirmed and an adequate trial and failure of loperamide AND an antispasmodic (e.g. dicyclomine) with an inadequate response or significant side effect/toxicity or have a contraindication to these therapies. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Gastroenterologist
Coverage Duration	Initial 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

VIIBRYD

Products Affected

- Trintellix oral tablet 10 mg, 20 mg, 5 mg
- Viibryd oral tablet 10 mg, 20 mg, 40 mg
- Viibryd oral tablets,dose pack 10 mg (7)- 20 mg (23)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have trial and failure or intolerance to 2 generic antidepressants from SSRI and SNRI classes.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

VIMPAT

Products Affected

- Vimpat intravenous
- Vimpat oral solution
- Vimpat oral tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of partial-onset seizures. Must have had an inadequate response or intolerance to 2 generic antiepileptic drugs (e.g. lamotrigine, topiramate, felbamate).
Age Restrictions	Age 17 years or older
Prescriber Restrictions	By or in consultation with a neurologist.
Coverage Duration	365 days
Other Criteria	Not Applicable

VOTRIENT

Products Affected

- Votrient

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

VRAYLAR

Products Affected

- Vraylar oral capsule 1.5 mg, 3 mg, 4.5 mg, 6 mg
- Vraylar oral capsule,dose pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have an adequate trial and failure or an inadequate response or intolerance to 2 generic antipsychotics (e.g., haloperidol, fluphenazine, chlorpromazine, perphenazine, aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone).
Age Restrictions	No Age Restrictions
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	365 days
Other Criteria	Not Applicable

XALKORI

Products Affected

- Xalkori oral capsule 200 mg, 250 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming ALK or ROS1 mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

XELJANZ

Products Affected

- Xeljanz
- Xeljanz XR

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Evidence of infection. Use of biologic disease-modifying antirheumatic drug or potent immunosuppressive agent (e.g. azathioprine, cyclosporine) in combination with tofacitinib. Severe hepatic impairment.
Required Medical Information	Diagnosis. Must have negative tuberculosis skin test. Must have moderately to severely active RA. Must have adequate trial and failure of etanercept and adalimumab with inadequate response or significant side effects/toxicity unless contraindicated. Must have lymphocyte count greater than or equal to 500 cells per cubic mm, ANC greater than or equal to 1000 cells per cubic mm, and Hgb level greater than or equal to 9g/dL. For reauth: must have documentation from the prescriber indicating stabilization or improvement in condition AND recent lymphocyte count, ANC, Hgb, lipid levels, liver function tests. Lymphocyte count, ANC, Hgb, lipid levels, liver function tests must be completed within 3 months of therapy initiation and at regular intervals thereafter.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Rheumatologist
Coverage Duration	Initial: 120 days. Reauth: 365 days.
Other Criteria	Not Applicable

XEOMIN

Products Affected

- Xeomin intramuscular recon soln 50 unit

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For blepharospasm: must have previous treatment with onabotulinumtoxinA. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

XERMELO

Products Affected

- Xermelo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For diarrhea: must be associated with carcinoid syndrome. Must have had a previous trial of a somatostatin analog (e.g., Sandostatin LAR) with failure or inadequate control of symptoms. Must be used in combination with a somatostatin analog. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

XGEVA

Products Affected

- Xgeva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Multiple myeloma. Concurrent treatment with denosumab (Prolia).
Required Medical Information	Diagnosis of prevention of skeletal-related events in patients with bone metastases from solid tumors. For giant cell tumor, must have disease that is unresectable or where surgical resection is likely to result in severe morbidity and member must be skeletally mature if less than 18 years of age. For hypercalcemia of malignancy: must have a trial and failure of IV bisphosphonate therapy (i.e. zoledronic acid 4mg/5mL or 4mg/100mL), with failure defined as an albumin-corrected calcium greater than 12.5mg/dL (3.1 mmol/L) despite recent treatment with an IV bisphosphonate.
Age Restrictions	Prevention of skeletal events, hypercalcemia of malignancy: age 18 years or older. Giant Cell Tumor: age 13 years or older.
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 Days
Other Criteria	Not Applicable

XIFAXAN

Products Affected

- Xifaxan oral tablet 550 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For hepatic encephalopathy: must have trial and failure of lactulose. For diarrhea-predominant irritable bowel syndrome (IBS-D): must have chart documentation of how the diagnosis was confirmed and an adequate trial and failure of loperamide AND an antispasmodic (e.g. dicyclomine) with an inadequate response or significant side effect/toxicity or have a contraindication to these therapies. Reauth for hepatic encephalopathy: must have chart documentation from prescriber indicating improvement in condition. Reauth for IBS-D: must have documentation from prescriber indicating recurrence of IBS-D symptoms after a successful treatment with rifaximin.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	Hepatic encephalopathy: 365 Days. IBS-D initial: 14 days. IBS-D reauth: 14 days.
Other Criteria	Criteria only applies to rifaximin 550mg. Criteria does not apply to rifaximin 200mg. For IBS-D: patients who experience a recurrence of symptoms can be retreated up to two times with the same dosage regimen.

XOLAIR

Products Affected

- Xolair

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For moderate to severe allergic asthma: must submit patient's weight, must have IgE level greater than or equal to 30 IU/mL AND positive skin or RAST test to perennial aeroallergen. Must have adequate trial of combination therapy with an ICS/LABA (inhaled corticosteroid/long-acting beta-agonist, such as Advair, Breo Ellipta, or Dulera) AND either a LAMA (long-acting muscarinic antagonist, such as Spiriva or Incruse Ellipta) or a leukotriene receptor antagonist (such as montelukast) with inadequate response or significant side effects/toxicities or have a contraindication to these therapies within the last year. Must have asthma symptoms that continue to be uncontrolled on optimized medication therapy regimen (uncontrolled defined as hospitalization for asthma within past year, requirement for oral or parenteral corticosteroids to control exacerbations of asthma on 2 occurrences in the past year, or need for daily corticosteroid with inability to taper off). For chronic idiopathic urticaria: must have chart documentation showing 3-month history of urticaria w/ presence of hives, must have adequate trial of one 2nd generation H1 antihistamine (e.g. levocetirizine) and one leukotriene antagonist (e.g. montelukast) with inadequate responses or significant side effects/toxicity unless contraindicated. For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Persistent asthma: 6 years of age or older. Idiopathic urticaria: 12 years of age or older.
Prescriber Restrictions	Urticaria: allergist, dermatologist, immunologist. Asthma: no prescriber restrictions.
Coverage Duration	Urticaria: 90 days initial, 365 days reauth. Asthma: 365 days.
Other Criteria	For asthma: must follow recommended dosing guidelines based upon weight and IgE level. For urticaria: dosages above 300mg every 4 weeks is not covered.

XTANDI

Products Affected

- Xtandi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have previous inadequate response or intolerance to abiraterone.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

XYREM

Products Affected

- Xyrem

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. For cataplexy associated with narcolepsy: must have chart documentation and sleep study to confirm diagnosis. For excessive daytime sleepiness associated with narcolepsy: must have polysomnographic evaluation and chart documentation supporting clinical history of narcolepsy AND must have an adequate trial and failure of 2 central nervous stimulants (e.g. modafinil, armodafinil, amphetamine salts, dextroamphetamine, methylphenidate). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Board-certified sleep specialist, pulmonologist, or neurologist
Coverage Duration	Initial: 90 days. Reauth: 365 days.
Other Criteria	Not Applicable

ZAVESCA

Products Affected

- Zavesca

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis of mild to moderate Type I Gaucher disease with any of the following: hepatomegaly (defined as liver size greater than or equal to 1.25 times normal), splenomegaly (defined as spleen size greater than 0.2% of body weight), or bone disease (defined as having one of the following: avascular necrosis, erlenmeyer flask deformity, lytic disease, marrow infiltrations, osteopenia, osteosclerosis, pathological fracture, or radiological evidence of joint deterioration), or bone marrow disease (defined as having anemia or thrombocytopenia). Must not have enzyme replacement therapy as therapeutic option (e.g. allergy/hypersensitivity to ERT, poor venous access, difficulties w/ infusion). For reauth: must have documentation from prescriber indicating improvement in condition.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	By or in consultation with a hematologist or physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration	365 days
Other Criteria	Not Applicable

ZELBORAF

Products Affected

- Zelboraf

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming BRAFV600E mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ZINBRYTA

Products Affected

- Zinbryta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Pre-existing hepatic disease or hepatic impairment, including ALT or AST 2 times the upper limit of normal. History of autoimmune hepatitis or other autoimmune condition involving the liver. Evidence of infection. Treatment currently with antineoplastic, immunosuppressive, or immune modulating therapies.
Required Medical Information	Diagnosis of relapsing form of multiple sclerosis (MS). Negative tuberculosis skin test. Must previously have had an inadequate response or intolerance to two of the following multiple sclerosis therapies: interferon beta-1a (Avonex), glatiramir (Copaxone), eginterferon beta-1a (Plegridy), and/or dimethyl fumarate (Tecfidera). Must have recent (within 6 months) assessment of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) with levels less than 2x upper limit of normal. For reauth: must have documentation from provider showing disease has improved or stabilized while on therapy, there is no infection, and monitoring of transaminases and bilirubin.
Age Restrictions	Age 17 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 180 days. Reauth: 365 days.
Other Criteria	Not Applicable

ZINPLAVA

Products Affected

- Zinplava

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Documentation of confirmed Clostridium difficile infection, as defined by passage of three or more loose stools within 24 hours and positive stool test for toxigenic CDI from a stool sample collected within 7 days of scheduled infusion. Must have high risk of CDI recurrence (65 years or older with a history of CDI in the past 6 months, immunocompromised state, or C. difficile ribotype 027). For reauth: must have documentation from provider indicating rationale for retreatment.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Gastroenterologist or infectious disease physician
Coverage Duration	1 dose per 365 days
Other Criteria	The safety and efficacy of repeat administration of bezlotoxumab in patients with CDI have not been studied.

ZOLINZA

Products Affected

- Zolinza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ZONTIVITY

Products Affected

- Zontivity

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Past history of stroke, transient ischemic attack, or intracranial hemorrhage. Current active pathological bleeding.
Required Medical Information	Past history of myocardial infarction within the past 2 weeks to 12 months or current diagnosis of peripheral artery disease. Must be on concomitant therapy with another antiplatelet agent, such as clopidogrel. Must have documentation of clinical rationale for use of vorapaxar and assessment of member's underlying risk of bleeding to show benefits of vorapaxar would outweigh risk of bleeding.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	Cardiologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ZORBTIVE

Products Affected

- Zorbtive

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Active malignancy
Required Medical Information	Diagnosis of Short Bowel Syndrome (defined as documented malabsorption from small intestines marked by diarrhea, malnutrition, and steatorrhea and that results from resection of the small intestine). Must be receiving adequate nutritional support as determined by prescriber. For reauth: must have documentation from prescriber indicating improvement in condition and clinical rationale for continuation of treatment.
Age Restrictions	Age 18 years or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	4 weeks
Other Criteria	Not Applicable

ZORTRESS

Products Affected

- Zortress

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Must have undergone solid organ transplant. Must have trial and failure (defined as intolerance to regimen or inability of regimen to prevent rejection at appropriate therapeutic dosing) of anti-rejection regimen containing at least 2 drugs (including cyclosporine, tacrolimus, azathioprine, mycophenolate mofetil, mycophenolate sodium) unless contraindicated.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a transplant specialist
Coverage Duration	365 Days
Other Criteria	B vs. D determination will be made prior to clinical criteria being applied.

ZOSTAVAX

Products Affected

- Zostavax (PF)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	None
Age Restrictions	Age 50 years or older
Prescriber Restrictions	No Prescriber Restrictions
Coverage Duration	1 dose per 365 days
Other Criteria	Not Applicable

ZURAMPIC

Products Affected

- Zurampic

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Severe renal impairment (CrCl less than 30mL/min), end stage renal disease, history of kidney transplant, on concomitant dialysis, tumor lysis syndrome, Lesch-Nyhan syndrome
Required Medical Information	Diagnosis. Must have documentation of symptomatic hyperuricemia and be on concurrent xanthine oxidase inhibitor therapy. Must not have achieved target serum acid levels with xanthine oxidase inhibitor monotherapy defined as a baseline serum uric acid level greater than or equal to 7mg/dL. Must have had at least 2 gout flares in the previous 12 months or a history of at least 1 gout tophus. Must have an adequate trial of combination therapy with a xanthine oxidase inhibitor (e.g. allopurinol or febuxostat) at maximum dosing (800mg/day for allopurinol and 80mg/day for febuxostat) and probenecid with an inadequate response or intolerance to a lower dose of the drug, unless contraindicated. Inadequate response defined as the inability to normalize uric acid to less than 6mg/dL. Must have tried to discontinue or reduce the dose of any medication(s) that may cause hyperuricemia (e.g. thiazide diuretics). For reauth: must have documentation of recent serum uric acid level from prescriber indicating improvement in serum uric acid level while on therapy and must continue to use lesinurad as combination therapy.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	By or in consultation with a Rheumatologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ZYDELIG

Products Affected

- Zydelig oral tablet 100 mg, 150 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ZYKADIA

Products Affected

- Zykadia

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis. Must have chart documentation of lab result confirming ALK mutation.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

ZYTIGA

Products Affected

- Zytiga

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	No Exclusion Criteria
Required Medical Information	Diagnosis.
Age Restrictions	No Age Restrictions
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	365 days
Other Criteria	Not Applicable

PART B VERSUS PART D

Products Affected

- Abelcet
- acetylcysteine
- acyclovir sodium intravenous solution
- Adrucil intravenous solution 500 mg/10 mL
- Akynzeo
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 mL, 1.25 mg/3 mL, 2.5 mg /3 mL (0.083 %), 5 mg/mL
- AmBisome
- amino acids 15 %
- Aminosyn 7 % with electrolytes
- Aminosyn 8.5 %-electrolytes
- Aminosyn II 10 %
- Aminosyn II 15 %
- Aminosyn II 7 %
- Aminosyn II 8.5 %
- Aminosyn II 8.5 %-electrolytes
- Aminosyn-HBC 7%
- Aminosyn-PF 10 %
- Aminosyn-PF 7 % (sulfite-free)
- Aminosyn-RF 5.2 %
- amiodarone intravenous solution
- amphotericin B
- aprepitant oral capsule 125 mg, 40 mg, 80 mg
- aprepitant oral capsule,dose pack
- Atgam
- azathioprine
- azathioprine sodium
- Bethkis
- bleomycin injection recon soln 30 unit
- Brovana
- budesonide inhalation
- Cancidas
- CellCept Intravenous
- cidofovir
- cladribine
- Clinimix 5%/D15W Sulfite Free
- Clinimix 5%/D25W sulfite-free
- Clinimix 2.75%/D5W Sulfit Free
- Clinimix 4.25%/D10W Sulf Free
- Clinimix 4.25%/D5W Sulfit Free
- Clinimix 4.25%-D20W sulf-free
- Clinimix 4.25%-D25W sulf-free
- Clinimix 5%-D20W(sulfite-free)
- Clinimix E 2.75%/D10W Sul Free
- Clinimix E 2.75%/D5W Sulf Free
- Clinimix E 4.25%/D10W Sul Free
- Clinimix E 4.25%/D25W Sul Free
- Clinimix E 4.25%/D5W Sulf Free
- Clinimix E 5%/D15W Sulfit Free
- Clinimix E 5%/D20W Sulfit Free
- Clinimix E 5%/D25W Sulfit Free
- Clinisol SF 15 %
- cromolyn inhalation
- cyclophosphamide oral capsule
- cyclosporine intravenous
- cyclosporine modified
- cyclosporine oral capsule
- Cyramza
- cytarabine
- cytarabine (PF) injection solution 2 gram/20 mL (100 mg/mL)
- Emend oral capsule 125 mg, 40 mg, 80 mg
- Emend oral capsule,dose pack
- Emend oral suspension for reconstitution
- Empliciti
- Engerix-B (PF) intramuscular syringe
- Engerix-B Pediatric (PF)
- fluorouracil intravenous solution 2.5 gram/50 mL
- Freamine HBC 6.9 %
- Gablofen intrathecal solution 10,000 mcg/20mL (500 mcg/mL), 40,000 mcg/20mL (2,000 mcg/mL)
- Gablofen intrathecal syringe 50 mcg/mL (1 mL)
- ganciclovir sodium
- Gengraf
- granisetron HCl oral
- Hepatamine 8%
- Intralipid intravenous emulsion 20 %
- Intralipid intravenous emulsion 30 %

- ipratropium bromide inhalation
- ipratropium-albuterol
- levalbuterol HCl
- Lioresal
- methotrexate sodium (PF)
- methotrexate sodium injection
- mycophenolate mofetil
- mycophenolate mofetil HCl
- mycophenolate sodium
- Nebupent
- Nephramine 5.4 %
- nitroglycerin intravenous
- ondansetron
- ondansetron HCl oral solution
- ondansetron HCl oral tablet 24 mg, 4 mg, 8 mg
- Perforomist
- Premasol 10 %
- Premasol 6 %
- Procalamine 3%
- Prograf intravenous
- Prosol 20 %
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL
- Recombivax HB (PF) intramuscular syringe
- Simulect intravenous recon soln 20 mg
- tacrolimus oral
- Thymoglobulin
- tobramycin in 0.225 % NaCl
- Travasol 10 %
- TrophAmine 10 %
- Trophamine 6%
- Vectibix intravenous solution 100 mg/5 mL (20 mg/mL)
- vinblastine intravenous solution
- Vincasar PFS intravenous solution 1 mg/mL
- vincristine intravenous solution 1 mg/mL

Details

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

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