ACITRETIN (S)

Products Affected

• Acitretin

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Severely impaired liver or kidney function. Chronic abnormally elevated blood lipid values. Concomitant use of methotrexate or tetracyclines. Pregnancy. Females of child-bearing potential who intend to become pregnant during therapy or at any time for at least 3 years after discontinuing therapy. Females of child-bearing potential who will not use reliable contraception while undergoing treatment and for at least 3 years following discontinuation. Females of child-bearing potential who drink alcohol during treatment or for two months after cessation of therapy.
Required Medical Information	Diagnosis of severe psoriasis
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ACTEMRA (BCBS RI)

Products Affected

• Actemra INJ 200MG/10ML, 400MG/20ML, 80MG/4ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis).
Required Medical Information	Diagnosis of one of the following: A) moderate to severe rheumatoid arthritis and patient had inadequate response to, intolerance to, or contraindication to one or more non-biologic disease-modifying anti-rheumatic drugs for at least 3 consecutive months, or B) systemic juvenile idiopathic arthritis and patient had inadequate response or intolerance to at least one oral systemic agent (i.e. NSAID, corticosteroid) glucocorticoids and dose does not exceed 8mg/kg greater than 30kg OR 12mg/kg less than 30kg C) Polyarticular Juvenile Idiopathic Arthritis AND Patient has had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs for at least 3 consecutive months
Age Restrictions	RA - 18 years of age or older. sJIA and pJIA - 2 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has been tested for TB and latent TB has been ruled out or is being treated. Approvable under Part D only if patient is in a long term care facility OR the medication is not being administered with an infusion pump.

ACTEMRA SC (BCBS RI)

Products Affected

• Actemra INJ 162MG/0.9ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis).
Required Medical Information	Diagnosis of moderate to severe rheumatoid arthritis and patient had inadequate response to, intolerance to, or contraindication to one or more non-biologic disease-modifying anti-rheumatic drugs for at least 3 consecutive months
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has been tested for TB and latent TB has been ruled out or is being treated per guidelines. For renewal, patient has stable disease or has improved on therapy (for RA, improvement in tender/swollen joint count, improvement in ACR scoring)

ACTIQ (BCBS RI)

Products Affected

• Fentanyl Citrate Oral Transmucosal

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Management of acute or post-operative pain, including headache/migraine, dental pain, or use in the emergency room. Opioid non-tolerant patients.
Required Medical Information	Patient meets the following: A) Diagnosis of cancer and use is for breakthrough cancer pain, B) patient is opioid tolerant and taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer, C) at least one other formulary short-acting strong narcotic analgesic alternatives (other than fentanyl) have been ineffective, not tolerated, or contraindicated, D) prescriber is registered in the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy Access program
Age Restrictions	16 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

ADAGEN (S)

Products Affected

• Adagen

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Severe thrombocytopenia
Required Medical Information	Diagnosis of adenosine deaminase (ADA) deficiency in a patient with severe combined immunodeficiency disease (SCID) AND patient is not a suitable candidate for, or who has failed, bone marrow transplantation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ADCIRCA (S)

Products Affected

• Adcirca

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Receiving nitrate therapy (includes intermittent use)
Required Medical Information	Diagnosis of pulmonary arterial hypertension WHO Group I with New York Heart Association (NYHA) Functional Class II or III that was confirmed by right heart catheterization
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial - 6 months. Renewal - 12 months
Other Criteria	N/A

ADEMPAS (S)

Products Affected

• Adempas

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Concomitant administration with nitrates or nitric oxide donors (such as amyl nitrate) in any form. Concomitant administration with phosphodiesterase inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline). Pregnancy.
Required Medical Information	Diagnosis of pulmonary arterial hypertension WHO group I with New York Heart Association Functional Class II or III AND diagnosis was confirmed by right heart catheterization OR Patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH, WHO group 4) AND patient has persistent or recurrent disease after surgical treatment (e.g., pulmonary endarterectomy) or has CTEPH that is inoperable AND female patients are enrolled in the ADEMPAS REMS program
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	6 months - initial. 12 months - renewal
Other Criteria	For renewal, medication was effective (i.e. improved 6 minute walk distance, oxygen saturation, etc.)

AFINITOR (S)

Products Affected

• Afinitor

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of advanced metastatic renal cell carcinoma and patient has failed therapy (disease progressed) with Sutent or Nexavar OR Diagnosis of progressive pancreatic neuroendocrine tumors (pNET) that are unresectable, locally advanced or metastatic OR Diagnosis of renal angiomyolipoma with tuberous sclerosis complex (TSC) and patient does not require immediate surgery OR Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer and patient is a postmenopausal woman and patient has failed treatment with Femara or Arimidex and the medication will be used in combination with Aromasin OR Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with TSC that requires therapeutic intervention but is not a candidate for curative surgical resection.
Age Restrictions	18 years of age or older for RCC, pNET, and renal angiomyolipoma with TSC. 1 year of age or older for SEGA
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

AFINITOR DISPERZ (S)

Products Affected

• Afinitor Disperz

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) that requires therapeutic intervention but is not a candidate for curative surgical resection.
Age Restrictions	1 year of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ALDURAZYME (S)

Products Affected

• Aldurazyme

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Hurler or Hurler-Scheie form of Mucopolysaccharidosis I (MPS I) or Diagnosis of Scheie form of MPS I with moderate to severe symptoms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ALECENSA (S)

Products Affected

• Alecensa

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of metastatic non-small cell lung cancer AND Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility AND Patient had an inadequate response, progressed on, or had an intolerance or contraindication to XALKORI (crizotinib)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	N/A

AMITIZA (S)

Products Affected

• Amitiza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Mechanical gastrointestinal obstruction.
Required Medical Information	Diagnosis of irritable bowel syndrome-constipation for at least 12 non-consecutive weeks and patient has tried and failed increasing fluid and fiber intake and patient has tried and failed or has an intolerance to osmotic laxatives, stimulant laxatives or probiotics and patient is female OR Diagnosis of chronic idiopathic constipation for at least 3 months and patient has tried and failed increasing fluid and fiber intake and patient has tried and failed or has an intolerance to osmotic laxatives, stimulant laxatives or stool softeners OR Diagnosis of chronic opioid-induced constipation due to non-cancer pain and patient has tried and failed a stool softener and a stimulant laxative AND Patient is not being treated with methadone
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Initial - 4 months. Renewal - 12 months
Other Criteria	For renewal, the patient has experienced an increase in the number of bowel movements.

AMPYRA (S)

Products Affected

• Ampyra

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	History of seizure. Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute).
Required Medical Information	Diagnosis of multiple sclerosis AND patient is ambulatory (able to walk at least 25 feet) AND patient has walking impairment
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial - 3 months. Renewal - 12 months
Other Criteria	For renewal, walking speed has improved from baseline.

ANADROL-50 (S)

Products Affected

• Anadrol-50

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Breast or prostate cancer in men. Breast cancer in women with hypercalcemia. Pregnancy. Nephrosis or nephrotic phase of nephritis. Severe hepatic dysfunction.
Required Medical Information	Diagnosis of anemia caused by deficient red cell production AND patient has tried and had an inadequate response or intolerance to standard therapies for anemia such as: erythropoietin stimulating agents, immunosuppressants, blood transfusions, etc. AND treatment will not replace other supportive measures (e.g., transfusion, iron supplementation, immunosuppressive therapy, corticosteroids, erythropoiesis-stimulating agents)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient experienced an objective improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions)

ARANESP (S)

Products Affected

Aranesp Albumin Free INJ 100MCG/0.5ML, 100MCG/ML, 10MCG/0.4ML, 150MCG/0.3ML, 200MCG/0.4ML, 200MCG/ML, 25MCG/0.42ML, 25MCG/ML, 300MCG/0.6ML, 300MCG/ML, 40MCG/0.4ML, 40MCG/ML, 500MCG/ML, 60MCG/0.3ML, 60MCG/ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Anemia due to myelodysplastic syndrome.
Exclusion Criteria	uncontrolled hypertension. Pure red cell aplasia that begins after ESA treatment.
Required Medical Information	Pre-treatment hemoglobin level less than 10 g/dL AND Patient has adequate iron stores prior to initiation of therapy defined as ferritin more than 100 mcg/L or serum transferrin saturation greater than 20% AND other causes of anemia such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic disease (such as sickle cell anemia, thalassemia, and porphyria) have been ruled out AND Diagnosis of one of the following: A) Anemia due to chronic kidney disease (CKD) with or without hemodialysis, OR B) Anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and two additional months of chemotherapy is anticipated C) anemia due to myelodysplastic syndrome (MDS) and endogenous serum erythropoietin level is 500 mUnits/mL or less
Age Restrictions	N/A
Prescriber Restrictions	CKD - prescribed by a nephrologist or hematologist. Non-myeloid malignancies, MDS - prescribed by an oncologist/hematologist.
Coverage Duration	Initial: 4 months. Renewal: CKD-12 months, Non-myeloid malignancies - 4 months

Other Criteria

For renewal of CKD, for dialysis patients: Hb less than 11 g/dL or physician will decrease or interrupt dose. For non-dialysis patients: Hb less than 10 g/dL or physician will decrease or interrupt dose. For renewal of non-myeloid malignancies: Concurrent myelosuppressive chemotherapy and Hb is 12g/dL or less and there is measurable response after eight weeks (defined as an increase in Hb 1 g/dL or more or a reduction in red blood cell transfusion requirements). For renewal of MDS, Hb is 12g/dL or less and there is measurable response after eight weeks (defined as an increase in Hb 1.5 g/dL or more or a reduction in red blood cell transfusion requirements) OR Patient will have a concomitant trial of G-CSF AND, if patient had concomitant trial of granulocyte colony-stimulating factor (G-CSF), patient had a measurable response as defined above after 8 weeks of G-CSF therapy. Excluded for ESRD patients on dialysis.

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ARCALYST (S)

Products Affected

• Arcalyst

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of cryopyrin-associated period syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS).
Age Restrictions	12 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with or recommendation of, an immunologist, allergist, dermatologist, rheumatologist, neurologist, or other medical specialist
Coverage Duration	12 months
Other Criteria	For renewal, patient experienced disease stability or improvement.

AUBAGIO (BCBS RI)

Products Affected

• Aubagio

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. First clinical episode with MRI features consistent with multiple sclerosis.
Exclusion Criteria	Severe hepatic impairment. Current treatment with leflunomide. Patients who are pregnant or women of childbearing potential not using reliable contraception.
Required Medical Information	Diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting MS or progressive-relapsing MS) OR patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis AND patient has had an inadequate response, intolerance or contraindication to Betaseron (interferon beta 1b), Avonex (interferon beta 1A) or Copaxone (glatiramer) Gilenya or Tecfidera
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient has experienced no or a decrease in the number of multiple sclerosis flare-ups.

AVASTIN (S)

Products Affected

• Avastin

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Gastrointestinal perforation. Wound dehiscence. Serious hemorrhage or recent hemoptysis.
Required Medical Information	Diagnosis of one of the following: A) First-line or second-line treatment of metastatic carcinoma of the colon or rectum in combination with IV 5-fluorouracil-based chemotherapy B) Second-line treatment of metastatic colorectal cancer in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy after progression on a first-line Avastin-containing regimen. C) First-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel, D) glioblastoma with progressive disease following prior therapy and the medication will be used as a single agent, E) metastatic renal cell carcinoma in combination with interferon alfa F) In combination with paclitaxel, peg-liposomal doxorubicin or topotecan for treatment of platinum-resistant recurrent epithelial ovarian, fallopian tube, or pirmary peritoneal cancer who received no more than two prior chemotherapy regimens, G) persistent, recurrent, or metastatic carcinoma of the cervix
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	BvD determination

BARACLUDE (BCBS RI)

Products Affected

• Baraclude SOLN

• Entecavir

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of chronic hepatitis B AND patient is HBsAg-positive for at least 6 months AND For HBeAg-positive patients, serum HBV DNA greater than 20,000 IU/mL (105 copies per mL) and for HBeAg-negative patients, serum HBV DNA greater than 2,000 IU/mL (104 copies/mL) AND Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) at least 2 times the upper limit of normal or histologically active disease (i.e. necroinflammation on biopsy) AND patient is receiving anti-retroviral therapy if the patient has HIV coinfection
Age Restrictions	2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient must be HBeAg negative and have not had HBsAg clearance OR HBeAg positive and have detectable HBV DNA and have not been anti-Hbe for at least 6 months.

BELEODAQ (S)

Products Affected

• Beleodaq

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of peripheral T-cell lymphoma AND patient has tried and had an inadequate response, intolerance or contraindication to at least one prior therapy (e.g., conventional chemotherapy)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

BENLYSTA (S)

Products Affected

• Benlysta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Receiving other biologic therapy or intravenous cyclophosphamide
Required Medical Information	Diagnosis of active, autoantibody-positive (acceptable assays include ANA, anti-ds-DNA, anti-Sm, etc.) systemic lupus erythematosus AND patient is currently receiving one or more of the following standard therapies: corticosteroids, antimalarials, NSAIDs, immunosuppressants
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

BENZODIAZEPINES (S)

Products Affected

- Alprazolam ORAL TABS
- Alprazolam Er ORAL TB24 1MG, 2MG, 3MG
- Alprazolam Intensol
- Alprazolam Odt
- Alprazolam Xr
- Chlordiazepoxide Hcl
- Clonazepam ORAL TABS
- Clonazepam Odt
- Clorazepate Dipotassium
- Diazepam CONC
- Diazepam ORAL SOLN

- Diazepam ORAL TABS
- Diazepam Intensol
- Estazolam
- Flurazepam Hcl
- Lorazepam CONC
- Lorazepam ORAL TABS
- Lorazepam Intensol
- Onfi ORAL TABS 10MG, 20MG
- Onfi SUSP
- Oxazepam
- Temazepam
- Triazolam

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	For alprazolam only: concomitant use with ketoconazole or itraconazole.
Required Medical Information	Verify the medication is being used for an FDA-approved diagnosis or compendial supported indication.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

BLINCYTO (S)

Products Affected

• Blincyto

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The patient has a diagnosis of B-cell precursor acute lymphoblastic leukemia AND The patient has Philadelphia chromosome-negative disease AND The patient's disease has relapsed or is refractory to previous treatment (e.g., chemotherapy, stem cell transplant)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	BvD determination

BONIVA IV (BCBS RI)

Products Affected

• Ibandronate Sodium INJ

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient is a postmenopausal female with osteoporosis AND Patient has a documented trial and failure of an oral bisphosphonate, where failure is defined as new fractures in compliant patient on therapy for at least 6 months, failure to produce a clinically significant change in biochemical markers of bone turnover, or a significant loss of bone mineral density on follow-up scans after 12-24 months of therapy OR documented contraindication or intolerance to oral bisphosphonate therapy or is unable to comply with appropriate administration recommendations for oral bisphosphonate therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient had an objective response to therapy. Approvable under Part D only if patient is in a long term care facility OR the medication is not being administered with an infusion pump.

BOSULIF (S)

Products Affected

• Bosulif

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Philadelphia chromosome-positive chronic myelogenous leukemia AND resistance, relapse, inadequate response to prior therapy with a tyrosine kinase inhibitor (TKI) AND if patient had mutation testing, patient does not have T315I or V299L mutation or intolerant to prior TKI therapy
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

BOTOX (S)

Products Affected

• Botox

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Achalasia. Lower limb spasticity due to stroke. Cervicogenic headache. Dysphagia. Salivation due to Parkinson's disease. Tourette's syndrome. Hemifacial spasm. Trigeminal neuralgia. Oromandibular dystonia. Tardive dyskinesia. Temporomandibular joint dysfunction.
Exclusion Criteria	Infection at the proposed injection site. Cosmetic use (e.g., wrinkles). For OAB and Urinary incontinence, patient has urinary tract infection or patient is not routinely performing clean intermittent self-catheterization (CIC) or is not willing/able to perform CIC if post-void residual urine volume is more than 200 mL.

Required Medical Information	Diagnosis of: A) strabismus, B) blepharospasm associated with dystonia, C) Urinary incontinence associated with neurologic condition and inadequate response to at least one antimuscarinic agent, unless contraindicated or intolerant to antimuscarinics (e.g., narrow angle glaucoma), D) Chronic migraine and Botox will be used as prophylaxis and experiences headaches on 15 or more days per month lasting four hours or longer and inadequate response with at least two first-line therapies from two different therapeutic classes (i.e. antiepileptics, beta-blockers, triptans, and tricyclic antidepressants), E) Cervical dystonia (including spasmodic torticollis) F) Overactive bladder and has symptoms (e.g., urge urinary incontinence, urgency, and frequency) and inadequate response to at least one antimuscarinic agent, unless contraindicated or intolerant to anti-muscarinics, G) Axillary hyperhidrosis refractory to topical aluminum chloride and condition significantly interferes with patient's daily activities, H) Upper limb spasticity and Botox will be used to improve muscle tone at wrist, elbow or finger flexors, I) lower limb spasticity due to stroke, J) achalasia and patient is not suitable for surgery, K) Cervicogenic headache and inadequate response to at least two therapies from two different therapeutic classes (e.g., NSAIDs, muscle relaxants, tricyclic antidepressants), L) Dysphagia/esophageal dysmotility, M) excessive salivation due to advanced Parkinson's disease, N) Gilles de la Tourette's syndrome and inadequate response to conventional agents (e.g., fluphenazine, haloperidol, pimozide), O) hemifacial spasm, P) refractory idiopathic trigeminal neuralgia and inadequate response to other therapies (e.g., carbamazepine, lamotrigine, or baclofen), Q) isolated oromandibular dystonia, R) tardive dyskinesia and patient failed other therapies (e.g., clozapine, risperidone, quetiapine) S) temporomandibular joint dysfunction
Age Restrictions	12 years of age or older - strabismus or blepharospasm. 18 years of age or older - axillary hyperhidrosis
Prescriber Restrictions	Urinary incontinence - prescribed by or in consultation with an urologist
Coverage Duration	12 months

Other Criteria

For renewal of cervical dystonia, patient experienced improvement in at least one of the following: pain, severity of abnormal head position, or effects on patient's daily activities. For renewal of blepharospasm, patient experienced an improvement in symptoms (e.g., ability to open eyes, improvement in blinking/spasms of the eye). For renewal of hemifacial spasm, excessive salivation due to Parkinson's disease, oromandibular dystonia, tardive dyskinesia, and hyperhidrosis, the patient experienced an improvement in symptoms. For renewal of strabismus, patient has improvement in vision or eye alignment. For renewal of migraine, patient experienced a decrease in the frequency of headaches. For renewal of OAB and urinary incontinence due to a neurologic condition, patient experienced an improvement in symptoms (e.g., urge urinary incontinence, urgency, and frequency). For renewal of upper limb spasticity, patient experienced an improvement in flexor muscle tone. For renewal of achalasia and dysphagia/esophageal dysmotility, improvement in dysphagia, chest pain and regurgitation. For renewal of cervicogenic headache, improvement in neck range of motion or pain. For renewal of Gilles de la Tourette's syndrome, improvement in blinking, blepharospasm, or dystonic tics. For renewal of trigeminal neuralgia, improvement in pain. For renewal of Temporomandibular joint dysfunction, improvement in pain, functioning, or tenderness. For renewal of lower limb spasticity, improvement in lower limb muscle tone, gait pattern, or walking distance.

BUPRENORPHINE/NALOXONE

Products Affected

• Suboxone

• Buprenorphine Hcl/naloxone Hcl

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of opioid dependence AND Prescription is a part of an overall treatment program (e.g., self-help groups, counseling, provide ongoing care, vocational training) AND Patient is not receiving any other opioids since starting therapy AND patient is not pregnant
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is certified through SAMHSA (Substance Abuse and Mental Health Services Administration) to prescribe Suboxone and provide registration number
Coverage Duration	Initial - 3 months. Renewal - 9 months
Other Criteria	For renewal, patient meets all initial criteria and prescriber is evaluating random urine drug screens and assessing the patient's progress (e.g., relapse, progress/accomplishment of treatment goals) and patient is not pregnant.

BUTRANS (S)

Products Affected

• Butrans

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Significant respiratory depression or severe bronchial asthma. Known or suspected paralytic ileus.
Required Medical Information	Patient has a diagnosis of severe pain requiring continuous, around-the-clock opioid analgesic for an extended period of time AND patient tried and failed, is unable to tolerate two generic extended-release opioid product and/or opioid combination product, unless the patient has documented swallowing difficulties.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

CABOMETYX (S)

Products Affected

• Cabometyx

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. RCC is advanced. History of failure, contraindication, or intolerance to at least one prior anti-angiogenic therapy [e.g., Nexavar (sorafenib), Sutent (sunitinib)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

CAPRELSA (S)

Products Affected

• Caprelsa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Congenital long QT syndrome
Required Medical Information	Diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

CAYSTON (S)

Products Affected

• Cayston

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of cystic fibrosis AND patient has evidence of P. aeruginosa in the lungs
Age Restrictions	7 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, Patient is benefiting from treatment (i.e. improvement in lung function [FEV1], decreased number of pulmonary exacerbations)

CELEBREX (S)

Products Affected

• Celecoxib ORAL CAPS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Hypersensitivity to celecoxib or sulfonamide drugs. History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Treatment of peri-operative pain in the setting of coronary artery bypass graft surgery. Active gastrointestinal bleeding
Required Medical Information	Patient has failed previous treatment or has an intolerance to at least one of the following: NSAIDs or salicylate OR patient is currently receiving treatment with any of the following: anticoagulants/antiplatelet drugs (i.e. warfarin, heparin, LMWH, Pradaxa, Plavix, etc.), antiulcer agents (i.e. proton pump inhibitors, histamine-2-receptor antagonists, or misoprostol), chronic use of oral corticosteroids, or methotrexate OR patient has a history of peptic ulcer disease or history of gastrointestinal bleed
Age Restrictions	PA applies to patients younger than 65 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

CERDELGA (S)

Products Affected

• Cerdelga

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Extensive or intermediate metabolizers taking a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor. Intermediate or poor metabolizers taking a strong CYP3A inhibitor.
Required Medical Information	The patient has a diagnosis of Gaucher disease type 1 AND patient is an extensive metabolizer, intermediate metabolizer, or poor metabolizer of CYP2D6 as detected by an FDA-cleared test
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient's condition has not progressed as defined by ALL of the following: hemoglobin level decreased by more than 1.5 g/dL from baseline, platelet count decreased more than 25% from baseline, spleen volume increased more than 25% from baseline, and liver volume increased more than 20% from baseline

CEREZYME (S)

Products Affected

• Cerezyme

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of type 1 Gaucher disease
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

CHOLBAM (S)

Products Affected

• Cholbam

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Medication will be used for the treatment of a bile acid synthesis disorder in a patient who has a single enzyme defect OR Medication will be used as adjunctive treatment for a peroxisomal disorder (including Zellwegger spectrum disorder) and patient exhibits one of the following: manifestation of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption.
Age Restrictions	N/A
Prescriber Restrictions	Hepatologist or pediatric gastroenterologist
Coverage Duration	Initial - 3 months. Renewal - 12 months
Other Criteria	For renewal, patient has experienced an improvement in liver function from baseline and patient has not experienced complete biliary obstruction or cholestasis while on therapy and treatment with Cholbam is being monitored by a hepatologist or pediatric gastroenterologist.

CIALIS 2.5 MG, 5 MG (S)

Products Affected

• Cialis ORAL TABS 2.5MG, 5MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use of nitrates. Diagnosis of erectile dysfunction without signs and symptoms of BPH.
Required Medical Information	Diagnosis of benign prostatic hyperplasia (BPH) and patient has experienced intolerance to or treatment failure with an alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g., dutasteride, finasteride)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

CIMZIA (R)

Products Affected

• Cimzia

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis)
Required Medical Information	Diagnosis of one of the following: A) moderate to severe rheumatoid arthritis and patient had an inadequate response to, intolerance to, or contraindication to ENBREL and HUMIRA B) moderate to severe Crohn's disease and patient had an inadequate response to, is intolerant to, or is contraindicated to at least one conventional therapy (corticosteroids [i.e. prednisone, methylprednisolone] or non-biologic DMARDs [i.e. azathioprine, methotrexate, mercaptopurine, etc.]) and HUMIRA C) psoriatic arthritis and patient had an inadequate response, intolerance to, or contraindication to HUMIRA and ENBREL D) ankylosing spondylitis and patient had an inadequate response to, intolerance to, or contraindication to HUMIRA and ENBREL.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	16 weeks (CD), 12 weeks (others). Renewal 12 months.
Other Criteria	Patient has been tested for TB and latent TB has been ruled out or is being treated. For renewal, patient has obtained a clinical response to therapy (e.g., for CD, symptomatic remission. For RA, improvement in tender/swollen joint count, improvement in ACR scoring. For PsA, improvement in number of swollen/tender joints, pain, stiffness. For AS, improvement in AS symptoms, such as stiffness and back pain) or patient's condition has stabilized.

CINRYZE (S)

Products Affected

• Cinryze

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	History of life-threatening immediate hypersensitivity reactions, including anaphylaxis to the product.
Required Medical Information	Diagnosis of hereditary angioedema AND Medication will be used for routine prophylaxis against angioedema.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

COMETRIQ (S)

Products Affected

• Cometriq

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Gastrointestinal perforation. Fistula. Severe hemorrhage.
Required Medical Information	Diagnosis of progressive, metastatic medullary thyroid cancer
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

COPAXONE (BCBS RI)

Products Affected

• Copaxone

• Glatopa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of relapsing-remitting multiple sclerosis OR diagnosis of first clinical episode with MRI features consistent with multiple sclerosis. Does the patient have significant lipodystrophy due to injection site reaction from Copaxone 20mg OR Has the patient consistently missed more than 6 doses / month of Copaxone 20mg over the last 6 months, as validated by RPH in claims data
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient has no or slowed disease progression

COSENTYX (R)

Products Affected

• Cosentyx

• Cosentyx Sensoready Pen

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis [TB])
Required Medical Information	Diagnosis of moderate to severe plaque psoriasis (affecting more than 5% of the body surface area or affecting crucial body areas such as the hands, feet, face, or genitals) AND patient tried and had an inadequate response, is intolerant of, or is contraindicated to HUMIRA and ENBREL AND the medication will not be used with other biologic agents
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has been tested for latent TB infection and latent TB has been ruled out or is being treated per guidelines. For renewal, patient has improved or stabilized while on therapy.

COTELLIC (S)

Products Affected

• Cotellic

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable or metastatic melanoma.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy. Melanoma: Patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib.

CYRAMZA (S)

Products Affected

• Cyramza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of one of the following: A) advanced gastric cancer or gastro-esophageal junction adenocarcinoma AND Patient had disease progression or intolerance to a prior chemotherapy regimen containing a fluoropyrimidine- or platinum-agent, B) metastatic non-small cell lung cancer AND CYRAMZA will be used in combination with docetaxel AND Patient had disease progression or intolerance to a prior chemotherapy regimen containing a platinum-agent AND If EGFR or ALK genomic tumor aberrations are present, the patient has had disease progression or intolerance to an approved targeted therapy (e.g., TARCEVA, GILOTRIF, XALKORI, ZYKADIA), or C) metastatic colorectal cancer and patient had disease progression on or after therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Cystaran (s)

Products Affected

• Cystaran

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of cystinosis AND Patient has corneal cystine crystal accumulation
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

DAKLINZA (S)

Products Affected

• Daklinza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitantly use with drugs that strongly induce cytochrome P450 enzyme (CYP) 3A, such as phenytoin, carbamazepine, rifampin, and St. John's wort
Required Medical Information	Patient has a diagnosis of chronic hepatitis C virus (HCV) genotype 1, 2, or 3 infection AND Patient will use the medication in combination with SOVALDI (sofosbuvir) AND Medication will not be used in combination with OLYSIO, TECHNIVIE, HARVONI, or VIEKIRA. G3 or G1 without cirrhosis: 12 weeks of therapy. G3 with cirrhosis and patient is ineligible for treatment with peginterferon alfa: 24 weeks. G1 with cirrhosis: 24 weeks. G2 - 12 to 24 weeks, where duration will be based on the AASLD treatment guidelines depending on patient's genotype, cirrhosis history, transplant history and previous treatment history.
Age Restrictions	N/A
Prescriber Restrictions	hepatologist, gastroenterologist, or infectious disease specialist
Coverage Duration	12 or 24 weeks as indicated in RMI section.
Other Criteria	N/A

DALIRESP (S)

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 (Child-Pugh B or C)
Required Medical Information	Diagnosis of severe chronic obstructive pulmonary disease (COPD) (defined as FEV1 less than or equal to 50% of predicted and FEV1/forced vital capacity [FVC] less than 0.7) associated with chronic bronchitis AND history of COPD exacerbations which requires the use of systemic corticosteroids, antibiotics, or hospital admission AND Medication will be used with a long-acting inhaled bronchodilator (i.e. long-acting anticholinergic, or long-acting beta agonist in combination with inhaled corticosteroid).
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

DARZALEX (S)

Products Affected

• Darzalex INJ 100MG/5ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma: Diagnosis of multiple myeloma.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy. Multiple myeloma: One of the following: a) Patient has received at least three prior treatment regimens which included both of the following: proteasome inhibitor (eg, bortezomib [Velcade], carfilzomib [Kyprolis]) and immunomodulatory agent (eg, lenalidomide [Revlimid], thalidomide [Thalomid]), or b) patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent.

DICLOFENAC GEL (S)

Products Affected

• Voltaren GEL

• Diclofenac Sodium GEL 1%

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Known hypersensitivity to diclofenac. Previously experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Use for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
Required Medical Information	Patient has a diagnosis of osteoarthritis of the knees or hands AND patient had experienced treatment failure with at least 2 prescription strength oral NSAIDs or patient has a documented swallowing disorder OR has a history of peptic ulcer disease/gastrointestinal bleeding OR patient is more than 65 years of age with one additional risk factor for gastrointestinal adverse event (e.g., use of anticoagulants or chronic corticosteroids)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

DIFFERIN (S)

Products Affected

• Adapalene CREA

• Adapalene EXTERNAL GEL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of mild to moderate acne vulgaris (including comedonal, cystic, and nodular)
Age Restrictions	PA applies to patients older than 26 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, medication has been effective in treating the patient's condition.

EGRIFTA (S)

Products Affected

• Egrifta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnant. Active malignancy (newly diagnosed or recurrent).
Required Medical Information	Diagnosis of excess abdominal fat secondary to HIV infection with lipodystrophy AND Patient has been receiving antiretroviral therapy AND waist circumference greater than 37.4 inches (men) or greater than 37 inches (women) AND waist-to-hip ratio greater than 0.94 (men) or greater than 0.88 (women)
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	For renewal, documentation that the patient has experienced a reduction from baseline in visceral adipose tissue as measured by waist circumference.

ELELYSO (BCBS RI)

Products Affected

• Elelyso

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of type 1 Gaucher disease confirmed by enzymatic testing AND 1 or more complication such as anemia, thrombocytopenia, bone disease, hepatomegaly, and splenomegaly AND will not be used in combination with Zavesca
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ELIGARD (S)

Products Affected

• Eligard

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of advanced or metastatic prostate cancer
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

EMPLICITI (S)

Products Affected

• Empliciti

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with Revlimid (lenalidomide) and dexamethasone.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy. Multiple myeloma: Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)].

EMSAM (S)

Products Affected

• Emsam

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pheochromocytoma. Patient is taking or will take any of the following: SSRIs, SNRIs, tricyclic antidepressants (TCAs), bupropion, buspirone, meperidine, tramadol, methadone, pentazocine, dextromethorphan, St. John's wort, mirtazapine, cyclobenzaprine, oral selegiline, other MAOIs, oxcarbazepine, carbamazepine, and/or sympathomimetic amines
Required Medical Information	Diagnosis of major depressive disorder AND Patient had adequate trial with at least 2 generic oral antidepressants from differing classes (at least one should be from the following list: selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, mirtazapine, or bupropion unless contraindicated), unless unable to take any oral medication AND Patient had an adequate washout period (for patients previously on agents requiring a washout period) AND Patients exceeding doses over 6mg/24 hours will be on a tyramine restricted diet (i.e. avoid aged/spoiled/fermented meat and cheese, tap beer, fava beans, or any foods with high amounts of tyramine)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, the patient has improved or stabilized on Emsam.

ENBREL (BCBS RI)

Products Affected

• Enbrel

• Enbrel Sureclick

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis). Currently taking cyclophosphasmide, other TNF antagonist, Anakinra, or Orencia
Required Medical Information	Diagnosis of one of the following: A) moderate to severe rheumatoid arthritis and patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs for at least 3 consecutive months B) moderate to severe polyarticular juvenile idiopathic arthritis and patient had an inadequate response, intolerance or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs) for at least 3 consecutive months C) psoriatic arthritis and patient had an inadequate response, intolerance, or contraindication to methotrexate D) ankylosing spondylitis and patient had an inadequate response, intolerance or contraindication to one or more NSAIDs E) moderate to severe chronic plaque psoriasis (affecting more than 5% of body surface area or affecting crucial body areas such as the hands, feet, face, or genitals) and patient had an inadequate response, intolerance or contraindication to conventional therapy with at least one of the following: phototherapy (including but not limited to Ultraviolet A with a psoralen [PUVA] and/or retinoids [RePUVA] for at least one continuous month or one or more oral systemic treatments (i.e. methotrexate, cyclosporine, acitretin, sulfasalazine) for at least 3 consecutive months.
Age Restrictions	2 years of age or older for JIA. 18 years of age or older for all other indications
Prescriber Restrictions	N/A
Coverage Duration	Initial 3 months (plaque psoriasis), 12 months (others). Renewal 12 months.

Other Criteria

Patient has been tested for TB and latent TB has been ruled out or is being treated. Dosing as per FDA approved labeling. For renewal, patient has stable disease or has improved while on therapy (e.g., for pJIA, reduction in disease flares, improvement in ACR scoring. For RA, improvement in tender/swollen joint count, improvement in ACR scoring. For PsA, improvement in number of swollen/tender joints, pain, stiffness. For AS, improvement in AS symptoms, such as stiffness and back pain).

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ENTRESTO (S)

Products Affected

• Entresto

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	History of angioedema related to previous ACE inhibitor or ARB therapy, concomitant use with aliskiren, pregnancy
Required Medical Information	Patient has a diagnosis of New York Heart Association class II to IV heart failure AND reduced ejection fraction less than or equal to 40% AND receiving concomitant therapy with one of the following beta blockers: carvedilol, bisoprolol, sustained-release metoprolol, unless unable to tolerate or contraindicated AND patient will discontinue use of any concomitant ACE inhibitor or ARB before initiating therapy, ACE inhibitors must be discontinued at least 36 hours prior to ENTRESTO
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ENTYVIO (R)

Products Affected

• Entyvio

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The patient has a diagnosis of one of the following: A) moderately to severely active Crohn's disease AND an inadequate response, intolerance, contraindication to at least one conventional therapy (e.g., corticosteroid or immunomodulator [azathioprine, methotrexate, or 6-merceptopurine]) and HUMIRA, OR B) moderately to severely active ulcerative colitis AND an inadequate response, intolerance, contraindication to a corticosteroid or an immunomodulator (i.e., azathioprine, 6-mercaptopurine) AND an inadequate response, intolerance, or contraindication to HUMIRA.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Initial: 14 weeks. Renewal: 12 months
Other Criteria	For renewal, patient has had a clinical response or clinical remission on therapy.

EPIDUO (S)

Products Affected

• Epiduo

• Epiduo Forte

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of mild to moderate acne vulgaris (including comedonal, cystic, and nodular)
Age Restrictions	PA applies to patients older than 26 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, medication has been effective in treating the patient's condition.

EPOETIN ALFA (S)

Products Affected

• Epogen

• Procrit

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Anemia secondary to hepatitis C. Anemia secondary to myelodysplastic syndrome.
Exclusion Criteria	uncontrolled hypertension. Pure red cell aplasia that begins after ESA treatment.
Required Medical Information	Pre-treatment hemoglobin level less than 10 g/dL (unless, for perioperative blood loss Hb should be greater than 10 but less than or equal to 13 g/dL) AND Patient has adequate iron stores prior to initiation of therapy defined as ferritin more than 100 mcg/L or serum transferrin saturation greater than 20% AND other causes of anemia such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic disease (such as sickle cell anemia, thalassemia, and porphyria) have been ruled out AND Diagnosis of one of the following: A) Anemia due to chronic kidney disease (CKD) with or without hemodialysis, OR B) Anemia in a patient with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and two additional months of chemotherapy is anticipated, C)Treatment of anemia in a patient at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusion, D) Anemia in zidovudine-treated HIV infection with serum erythropoietin levels 500 mUnits/mL or less and zidovudine doses 4,200 mg/week or less E) Anemia secondary to hepatitis C therapy and patient is receiving ribavirin and interferon/peginterferon F) Anemia due to myelodysplastic syndrome and endogenous serum erythropoietin level is 500 mUnits/mL or less.
Age Restrictions	N/A
Prescriber Restrictions	CKD - prescribed by a nephrologist or hematologist. Non-myeloid malignancies , MDS - prescribed by an oncologist/hematologist. Surgery - Prescribed by a surgeon. HIV - Prescribed by an infectious disease specialist. HCV - ID specialist or gastroenterologist
Coverage Duration	Initial: 4 mos (others). Renewal: CKD-12 mos, Others -4 mos. Sx-3 mos

Other Criteria

For renewal of CKD, for dialysis patients: Hb less than 11 g/dL or physician will decrease or interrupt dose and for non-dialysis patients: Hb less than 10 g/dL or physician will decrease or interrupt dose. For renewal of non-myeloid malignancies: Concurrent myelosuppressive chemotherapy and Hb is 12g/dL or less and there is measurable response after eight weeks (defined as an increase in Hb 1 g/dL or more or a reduction in red blood cell transfusion requirements). For renewal of zidovudine-treated HIV, Hb is 12g/dL or less AND Zidovudine dose remains 4,200 mg/week or less and there is a measurable response after eight weeks (defined as an increase in Hb or a reduction in RBC transfusion requirements or documented dose escalation [up to max of 300 units/kg/dose]). For renewal of MDS, Hb is 12 g/dL or less and patient had HB rise of 1.5g/dL or a decrease in RBC transfusion requirements after at least 8 weeks of treatment OR patient will have a concomitant trial with G-CSF AND if patient had concomitant trial with G-CSF, patient had a measureable response to therapy after at least 8 weeks. For renewal of HCV, Hb 12 or less and concurrent ribavirin/interferon or pegylated interferon/ribavirin therapy. ESRD patients on dialysis excluded.

ERIVEDGE (S)

Products Affected

• Erivedge

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of metastatic basal cell carcinoma OR Diagnosis of locally advanced basal cell carcinoma that has recurred following surgery or when the patient is not a candidate for surgery and radiation
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ERWINAZE (S)

Products Affected

• Erwinaze

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Member has experienced any of the following with prior asparaginase therapy: serious hypersensitivity reactions, including anaphylaxis, serious pancreatitis, serious thrombosis, serious hemorrhagic events
Required Medical Information	Diagnosis of acute lymphoblastic leukemia AND Patient has a hypersensitivity to E. coli-derived asparaginase
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ESBRIET (S)

Products Affected

• Esbriet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The patient has a diagnosis of idiopathic pulmonary fibrosis confirmed by a high resolution CT scan or biopsy AND the patient does not have evidence or suspicion of an alternative interstitial lung disease diagnosis AND liver function tests have been performed prior to start of therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	For renewal, patient experienced stabilization from baseline or a less than 10 percent decline in force vital capacity AND the patient has not experienced AST or ALT elevations greater than 5 times the upper limit of normal or greater than 3 times the upper limit of normal with signs or symptoms of severe liver damage.

EXALGO (S)

Products Affected

• Hydromorphone Hcl Er

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Significant respiratory depression. Acute or severe bronchial asthma. Known or suspected paralytic ileus. Gastrointestinal obstruction.
Required Medical Information	Diagnosis of severe pain requiring continuous, around-the-clock opioid analgesic for an extended period of time AND patient has tried and failed or unable to tolerate at least two generic extended-release opioid products, such as: oxymorphone ER, morphine ER, fentanyl, methadone, tramadol ER AND Patient is opioid tolerant, taking at least 60 mg oral morphine per day, 25 µg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, or an equianalgesic dose of another opioid for a week or longer.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

EXJADE (S)

Products Affected

• Exjade

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Myelodysplastic syndrome in a patient with Low or Intermediate-1 disease or is a potential transplant patient and who has received more than 20 red blood cell transfusions.
Exclusion Criteria	Creatinine clearance less than 40 mL/minute. Platelet count less than 50 x 109/L. Poor performance status. Severe (Child-Pugh class C) hepatic impairment. High-risk myelodysplastic syndromes. Advanced malignancies. Gastrointestinal ulceration or hemorrhage.
Required Medical Information	Patient has a diagnosis of one of the following: A) chronic iron overload due to blood transfusions and patient has a baseline ferritin level more than 1,000 mcg/L and the patient has required the transfusion of at least 100 mL/kg packed red blood cells OR B) chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) and liver iron concentration (LIC) is 5 mg of iron per gram of liver dry weight (mg Fe/g dw) or higher and serum ferritin level is greater than 300 mcg/L OR C) Myelodysplastic syndrome (MDS) AND The patient has Low or Intermediate-1 disease or is a potential transplant patient and patient has received more than 20 red blood cell transfusions
Age Restrictions	2 years of age or older for chronic iron overload due to transfusions. 10 years of age or older for chronic iron overload due to NTDT
Prescriber Restrictions	N/A
Coverage Duration	NTDT - 6 months. Transfusion-dependent anemia, MDS - 12 months.
Other Criteria	For renewal of chronic iron overload due to blood transfusions and MDS, the experienced a reduction in serum ferritin level or LIC. For renewal of chronic iron overload due to NTDT, patient has LIC 3 mg Fe/g dw or higher and patient experienced a reduction in serum ferritin level or LIC.

FABRAZYME (S)

Products Affected

• Fabrazyme INJ 35MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Fabry disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

FARYDAK (S)

Products Affected

• Farydak

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of multiple myeloma AND Patient has received at least 2 prior therapies, including Velcade and an immunomodulatory agent (e.g., Revlimid, Thalomid, or Pomalyst) or has a contraindication or intolerance to both Velcade and an immunomodulatory agent AND Farydak will be used in cominbation with Velcade (unless contraindicated) and dexamethasone.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

FENTANYL (S)

Products Affected

- Abstral
- Fentora

- Lazanda
- Subsys

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Management of acute or post-operative pain, including headache/migraine, dental pain, or use in the emergency room. Opioid non-tolerant patients.
Required Medical Information	Patient meets the following: A) Diagnosis of cancer and use is for breakthrough cancer pain, B) patient is opioid tolerant and taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer, C) at least one other formulary short-acting strong narcotic analgesic alternatives (other than fentanyl) have been ineffective, not tolerated, or contraindicated, D) prescriber and patient are registered in the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy Access program, E) for brand requests, generic transmucosal fentanyl citrate has been ineffective or not tolerated.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

FERRIPROX (S)

Products Affected

• Ferriprox

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of transfusional iron overload due to thalassemia syndromes AND patient has failed prior chelation therapy with Desferal or Exjade (failure is defined as a serum ferritin level greater than 2,500 mcg/L) or patient has a contraindication or intolerance to Desferal or Exjade AND Patient has an absolute neutrophil count greater than 1.5 x 109/L.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient has experienced at least a 20% reduction in serum ferritin levels and has an absolute neutrophil count greater than 0.5 x 109/L

FIRAZYR (S)

Products Affected

• Firazyr

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of hereditary angioedema AND medication will be used for the treatment of acute attacks.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

FIRMAGON (S)

Products Affected

• Firmagon

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of advanced or metastatic prostate cancer
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

FLECTOR (S)

Products Affected

• Flector

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Previously experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Use for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery. Application to non-intact or damaged skin.
Required Medical Information	Patient is experiencing acute localized pain due to minor strains, sprains and contusions AND the intended duration of therapy is 3 months or less AND patient had experienced treatment failure with at least 2 prescription strength oral NSAIDs or patient has a documented swallowing disorder OR has a history of peptic ulcer disease/gastrointestinal bleeding OR patient is more than 65 years of age with one additional risk factor for gastrointestinal adverse event (e.g., use of anticoagulants or chronic corticosteroids)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

FORTEO (BCBS RI)

Products Affected

• Forteo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Underlying hypercalcemia disorder such as primary hyperparathyroidism
Required Medical Information	Patient has a diagnosis of one of the following: a) osteoporosis in a postmenopausal female, b) primary or hypogonadal osteoporosis in a male, or c) osteoporosis associated with sustained systemic glucocorticoid therapy AND patient is considered to be at high-risk for fracture by meeting one or more of the following: A) history of osteoporotic fracture, B) multiple risk factors for facture (including older age, female gender, prior osteoporotic fracture, low body mass index, rheumatoid arthritis, smoker, alcohol intake more than 3 drinks/day, parental history of hip fracture, oral glucocorticoid therapy or patient ever took prednisone at a dose of 5 mg or higher), or C) documented trial and failure of bisphosphonate, or D) documented contraindication or intolerance to bisphosphonate therapy. Patient has not received more than 2 years of therapy with Forteo.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve doses based on FDA labeling

GATTEX (S)

Products Affected

• Gattex

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active gastrointestinal malignancy (gastrointestinal tract, hepatobiliary, pancreatic), colorectal cancer, or small bowel cancer
Required Medical Information	Diagnosis of short bowel syndrome AND patient is receiving specialized nutritional support (i.e. parenteral nutrition)
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient has a reduced need for parenteral support (20% reduction) after at least 6 months of therapy.

GAZYVA (S)

Products Affected

• Gazyva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of chronic lymphocytic leukemia (CLL) AND patient is treatment naïve AND Gazyva will be used in combination with chlorambucil AND patient has been screened for hepatitis B virus infection and does not have HBV reactivation and diagnosis of progressive multifocal leukoencephalopathy will be considered in any patient presenting with new onset or changes to pre-existing neurologic manifestations and discontinued if PML develops
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

GILENYA (BCBS RI)

Products Affected

• Gilenya

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. First clinical episode with MRI features consistent with multiple sclerosis.
Exclusion Criteria	Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. Baseline QTc interval greater than or equal to 500 ms. Receiving concurrent treatment with Class Ia or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol, bretylium, disopyramide, dofetilide, ibutilide). Or concomitant therapy with antineoplastics, immunosuppressants, and immunomodulating therapy.
Required Medical Information	Diagnosis of a relapsing form of multiple sclerosis or diagnosis of first clinical episode with MRI features consistent with MS AND Patient will be observed for signs and symptoms of bradycardia in a controlled setting for at least 6 hours after the first dose. Inadequate response to a previous trial of 1 injectable (interferon beta or glatiramer) Immunity to varicella: history of chickenpox, vaccinated against varicella zoster virus and positive antibody testing AND patients who are not currently stable on therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial - 6 months. Renewal - 12 months
Other Criteria	For renewal, the patient has experienced a reduction in the number of MS relapses, improvement in object symptoms scores, or has not had MRI progression.

GILOTRIF (S)

Products Affected

• Gilotrif

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer AND patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions of exon 21 (L858R) substitution mutation as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility AND the medication will be used first-line.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

GLEEVEC (S)

Products Affected

• Gleevec

• Imatinib Mesylate

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following in an adult: A) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), B) Ph+ acute lymphoblastic leukemia (ALL), C) Gastrointestinal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy, D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, E) hypereosinophilic syndrome or chronic eosinophilic leukemia, F) myelodysplastic syndrome or myeloproliferative disease associated with platelet-derived growth factor receptor gene rearrangements, G) aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown. Diagnosis of one of the following in a pediatric patient: A) Ph+CML that is newly diagnosed in the chronic phase B) newly diagnosed Ph+ ALL
Age Restrictions	18 years of age or younger - newly diagnosed CML in the chronic phase or newly diagnosed Ph+ ALL. 18 years of age or older for other indications.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

GRALISE (BCBS RI)

Products Affected

• Gralise

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of post-herpetic neuralgia and patient has tried and failed a dose of at least 1800 mg of generic gabapentin or patient has experienced intolerance to generic gabapentin
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient has improvement in pain severity.

GROWTH HORMONE (S)

Products Affected

- Genotropin
- Genotropin Miniquick
- Humatrope INJ 12MG, 24MG, 6MG
- Humatrope Combo Pack
- Norditropin Flexpro
- Nutropin Aq Nuspin 10
- Nutropin Aq Nuspin 20

- Nutropin Aq Nuspin 5
- Nutropin Aq Pen
- Omnitrope
- Saizen
- Saizen Click.easy
- Tev-tropin
- Zomacton

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Growth hormone deficiency (GHD). Small for gestational age (SGA). Chronic renal insufficiency (CRI). Short stature homeobox-containing gene (SHOX) deficiency. Noonan syndrome. Prader-Willi Syndrome (PWS). Turner Syndrome. Adult- or childhood-onset GHD.
Exclusion Criteria	Child with closed epiphyses. Acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure. Active malignancy. Active proliferative or severe non-proliferative diabetic retinopathy. For PWS only: sever obesity, history of upper airway obstruction or sleep apnea, or severe respiratory impairment.

Required Medical Information	Diagnosis of pediatric indication: A) GHD and one stim test with peak GH secretion below 10 ng/mL or IGF-1/IGFBP3 level more than 2 SDS below mean if CNS pathology, h/o irradiation, or proven genetic cause, B) SGA and birth wt or length 2 or more SDS below mean for gestational age and fails to manifest catch up growth by age 2 (height [ht] 2 or more SDS below mean for age and gender), C) CRI and nutritional status optimized, metabolic abnormalities corrected, and not had renal transplant D) SHOX deficiency or Noonan syndrome E) PWS confirmed by genetic testing AND ht below 3rd percentile or growth velocity (GV) measured over 1 year more than 2 SD below mean for age and sex, F) Turner Syndrome confirmed by chromosome analysis and ht below 5th percentile for age and sex. For GHD, CRI, SHOX deficiency, and Noonan syndrome, one of the following: ht more than 3 SDS below mean for age and gender, or ht more than 2 SDS below mean with GV more than 1 SDS below mean, or GV over 1 year 2 SDS below mean. OR Diagnosis of adult indication: A) childhood- or adult-onset GHD confirmed by 2 standard GH stim tests (provide assay): 1 test must be insulin tolerance test (ITT) with blood glucose nadir less than 40 mg/dL (2.2 mmol/L). If contraindicated, use a standardized stim test (i.e. arginine plus GH releasing hormone [preferred], glucagon, arginine), B) GHD with at least 1 other pituitary hormone deficiency and failed at least 1 GH stim test (ITT preferred), C) GHD with panhypopituitarism (3 or more pituitary hormone deficiencies), D) GHD with irreversible hypothalamic-pituitary structural lesions due to tumors, surgery or radiation of pituitary or hypothalamus region AND a subnormal IGF-1 (after at least 1 month off GH therapy) AND Objective evidence of GHD complications, such as: low bone density, increased visceral fat mass, or CV complications AND Completed linear growth (GV less than 2 cm/year) AND GH has been discontinued for at least 1 month (if previously receiving GH).
Age Restrictions	SGA more than 2 years of age
Prescriber Restrictions	CRI: nephrologist. Others - endocrinologist
Coverage Duration	12 months
Other Criteria	Patient has tried and had an inadequate response or intolerance to Norditropin or Nutropin/Nutropin AQ. For renewal of pediatric indications, final adult height has not been reached as determined by the fifth percentile of adult height and growth velocity is more than 2 cm/year. For renewal of adult indications, patient has experienced an improvement or normalization of IGF-1 levels (not a requirement in patients with panhypopituitarism

H.P. ACTHAR GEL (BCBS RI)

Products Affected

• H.p. Acthar

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of infantile spasms OR treatment of acute exacerbation of multiple sclerosis in a patient has tried and had an inadequate response, intolerance, or contraindication to corticosteroid therapy OR The prescriber has provided clinical support from at least one clinical study from a peer-reviewed journal and patient has tried and failed had an inadequate response, intolerance, or contraindication to corticosteroid therapy and meets one of the following: A) During an exacerbation of systemic lupus erythematosus (SLE), B) SLE as maintenance treatment C) systemic dermatomyositis (polymyositis) D) adjunctive therapy for short-time use for an acute episode/exacerbation in psoriatic arthritis and patient is currently receiving maintenance treatment for the condition (i.e. methotrexate or TNF inhibitor), E) adjunctive therapy for short-time use for an acute episode/exacerbation in rheumatoid arthritis or juvenile idiopathic arthritis and patient is currently receiving maintenance treatment for the condition (i.e. nonbiologic DMARDs, TNF inhibitor, or other biologic response modifier), F) adjunctive therapy for short-time use for an acute episode/exacerbation in ankylosing spondylitis and patient is currently receiving maintenance treatment for the condition (i.e. NSAIDs, TNF inhibitor), G) severe erythema multiforme, Stevens-Johnson syndrome, H) serum sickness, I)severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation, J) symptomatic sarcoidosis, K) to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
Age Restrictions	2 years of age or younger for diagnosis of IS, 18 years of age or older in MS
Prescriber Restrictions	N/A

Coverage Duration	IS-plan year, Collagen diseases - 6 months. Others- 1 month
Other Criteria	For rheumatic disorders: Failure of 12 week course of corticosteroid and concomitant therapy with a 3 month course of biologic DMARD. For MS: Failure of 3 to 5 day course of corticosteroid and concomitant use of a 3 month course of an immunomodulator

HALAVEN (S)

Products Affected

• Halaven

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded by Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of metastatic breast cancer AND member has tried and failed an anthracycline and a taxane.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

HARVONI (BCBS RI)

Products Affected

• Harvoni

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Currently receiving hepatitis C treatment for genotype 1. Concomitant use with one of the following medications: Rifampin, carbamazepine, phenobarbital, phenytoin, oxcarbazepine, rifabutin, rifapentine, St. John's Wort, tipranavir (Aptivus), acid reducing medication - daily dose does not exceed Prevacid 30 mg, omeprazole 20 mg, Protonix 40 mg, Aciphex 20 mg, Nexium 20 mg, Zantac 150 mg twice daily, Pepcid 40 mg twice daily. Received other hepatitis treatment within the previous 12 months (except F3/F4 cirrhotic patients who completed a regimen but did not achive SVR).
Required Medical Information	Patient has a diagnosis of chronic hepatitis C virus (HCV) genotype 4, 5 or 6 infection or HCV genotype 1 infection (mixed genotypes are not eligible) AND Harvoni will be used as monotherapy unless Harvoni will be used in combination with RBV for the following situations: post liver transplant patients, sofosbuvir/RBV/PEG or SOF/RBV treatment experienced patients, PEG/RBV +/- PI (Incivek, Victrelis) treatment experienced patients WITH cirrhosis
Age Restrictions	N/A
Prescriber Restrictions	hepatologist, gastroenterologist, or infectious disease specialist
Coverage Duration	G4,5,6: 12 weeks. G1 infection: See Other Criteria.
Other Criteria	12 wks, unless patient is genotype 1 with cirrhosis G1 and failed prior PEG+RBV with or without a protease inhibitor, SOF regimen, or SOF + SMV OR post-transplant patients (G1 or G4) who are RBV intolerant, then approve for 24 weeks.

HEPSERA (S)

Products Affected

• Adefovir Dipivoxil

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of chronic hepatitis B AND patient is HBsAg-positive for at least 6 months AND For HBeAg-positive patients, serum HBV DNA greater than 20,000 IU/mL (105 copies per mL) and for HBeAg-negative patients, serum HBV DNA greater than 2,000 IU/mL (104 copies/mL) AND Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) at least 2 times the upper limit of normal or histologically active disease (i.e. necroinflammation on biopsy)
Age Restrictions	12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient must be HBeAg negative and have not had HBsAg clearance OR HBeAg positive and have detectable HBV DNA and have not been anti-Hbe for at least 6 months

HERCEPTIN (S)

Products Affected

• Herceptin

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following: A) HER2 overexpressing breast cancer AND patient is node positive OR node negative and either ER/PR negative or ER/PR positive with one high risk feature (i.e. pathological tumor size greater than 2 cm, Grade 2-3, or age less than 35 years) AND medication is for adjuvant treatment as part of a regimen consisting of: doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel OR with docetaxel and carboplatin OR as a single agent following multimodality anthracycline-based therapy, B) HER2+ metastatic breast cancer and medication will be used as neoadjuvant treatment in a member with locally advanced, inflammatory or early stage disease (either greater than 2 cm in diameter or node positive) and Herceptin is used in combination with pertuzumab and docetaxel C) HER2-overexpressing metastatic breast cancer AND medication will be used in combination with paclitaxel for first-line treatment OR as a single agent in a patient who received one or more chemotherapy regimens for metastatic disease OR in combination with Perjeta (pertuzumab) in a patient who has not received prior anti-HER2 therapy (e.g., trastuzumab) or chemotherapy for metastatic disease OR in combination with Tykerb (lapatinib) as second-line treatment of HER2+ recurrent or metastatic disease, D) HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma AND patient has not received prior treatment for metastatic disease AND medication will be used in combination with cisplatin and capecitabine or 5-fluorouracil
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months

Other Criteria

Prescriber has assessed the patient's cardiac function/left ventricular ejection fraction prior to initiation of therapy. Female patients of child-bearing potential have been advised of the risk of embryo-fetal death and birth defects and the need for effective contraception during and after Herceptin treatment. Pregnancy status will be verified prior to initiation of Herceptin.

HETLIOZ (S)

Products Affected

• Hetlioz

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Non-24-hour-sleep-wake disorder (Non-24) AND patient has documented blindness
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months (initial), 12 months (renewal)
Other Criteria	For renewal, patient experienced an objective improvement (e.g., improvement in timing of nighttime sleep, improvement in duration of nighttime sleep, or reduction in daytime sleep).

HEXALEN (S)

Products Affected

• Hexalen

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of persistent or recurrent ovarian cancer AND the medication will be used as palliative treatment AND the medication will be used as a single agent AND the medication will be used following first-line therapy with a cisplatin and/or alkylating agent-based combination.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

HORIZANT (S)

Products Affected

• Horizant

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of moderate to severe primary restless leg syndrome and patient has experienced treatment failure or is intolerant to ropinirole or pramipexole OR Patient has a diagnosis of post-herpetic neuralgia and patient tried and failed a dose of at least 1800 mg of generic gabapentin or patient has experienced intolerance to generic gabapentin
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient had a measurable response to therapy (e.g. decrease in symptoms onset or severity, improved sleep, decrease in symptom intensity for RLS or decreased pain severity for PHN)

HRM - ANALGESICS

Products Affected

- Indomethacin ORAL CAPS
- Indomethacin Er
- Ketorolac Tromethamine TABS
- Meperidine Hcl INJ

- Meperidine Hcl ORAL SOLN
- Meperidine Hcl ORAL TABS
- Pentazocine/naloxone Hcl
- Talwin

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Mild pain: acetaminophen, codeine. Moderate to severe pain: short-term NSAIDs, tramadol, tramadol/APAP, morphine sulfate, hydrocodone/APAP, oxycodone, oxycodone/APAP, fentanyl. Not covered for members enrolled in a Medicare approved hospice program

HRM - ANTIDEPRESSANTS

Products Affected

- Amitriptyline Hcl ORAL TABS
- Chlordiazepoxide/amitriptyline
- Clomipramine Hcl ORAL CAPS
- Doxepin Hcl CONC
- Doxepin Hcl ORAL CAPS

- Imipramine Hcl ORAL TABS
- Imipramine Pamoate
- Perphenazine/amitriptyline
- Surmontil
- Trimipramine Maleate ORAL CAPS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only.TCA: nortriptyline, desipramine, low-dose doxepin, trazodone. Depression: SSRI, SNRI, mirtazapine, bupropion. duloxetine, gabapentin.

HRM - ANTIEMETIC DRUGS

Products Affected

- Diphenhydramine Hcl CAPS 50MG
- Pharbedryl CAPS 50MG
- Phenadoz
- Phenergan RECTAL SUPP
- Promethazine Hcl INJ

- Promethazine Hcl ORAL TABS
- Promethazine Hcl RECTAL SUPP
- Promethazine Hcl SYRP
- Promethazine Hcl Plain
- Promethegan
- Trimethobenzamide Hcl CAPS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Not covered for members enrolled in a Medicare approved hospice program.

HRM - ANTIHISTAMINES

Products Affected

- Arbinoxa
- Carbinoxamine Maleate
- Clemastine Fumarate SYRP
- Clemastine Fumarate TABS 2.68MG
- Cyproheptadine Hcl SYRP
- Cyproheptadine Hcl TABS

- Diphenhydramine Hcl INJ
- Hydroxyzine Hcl INJ
- Hydroxyzine Hcl ORAL TABS
- Hydroxyzine Hcl SYRP
- Hydroxyzine Pamoate ORAL CAPS
- Promethazine Vc Plain
- Promethazine/phenylephrine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indicationAND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

HRM - ANTIHYPERTENSIVE AGENTS

Products Affected

• Guanfacine Hcl

• Reserpine ORAL TABS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Requires trial of at least one Non-HRM alternative: Low dose thiazide or a second generation calcium channel blocker OR ACE inhibitor, ARB, beta-blocker or combination product based on specific chronic conditions

HRM - ANTI-INFECTIVE (BCRI)

Products Affected

- Macrodantin CAPS 25MG
- Nitrofurantoin SUSP
- Nitrofurantoin Macrocrystals

- Nitrofurantoin Monohydrate
- Nitrofurantoin
 Monohydrate/macrocrystals

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) when used longer than 90 cummulative days and wishes to proceed with the originally prescribed medication AND intended duration of therapy will be verified
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) when used longer than 90 days and wishes to proceed with the originally prescribed medication AND intended duration of therapy will be verified.

HRM - ANTIPARKINSON AGENTS

Products Affected

• Benztropine Mesylate INJ

- Benztropine Mesylate ORAL TABS
- Trihexyphenidyl Hcl

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indicationAND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

HRM - CALCIUM CHANNEL BLOCKERS, DIHYDROPYRIDINE

Products Affected

• Nifedipine ORAL CAPS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	extended-release nifedipine, nicardipine, amlodipine

HRM - DEMENTIA AGENTS

Products Affected

• Ergoloid Mesylates TABS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Requires trial of at least one Non-HRM alternative: donepezil, galantamine, rivastigmine, memantine

HRM - ENDOCRINE, ORAL AND TRANSDERMAL ESTROGENS AND PROGESTINS

Products Affected

- Fyavolv
- Jevantique Lo

 Norethindrone Acetate/ethinyl Estradiol ORAL TABS 2.5MCG;
 0.5MG, 5MCG; 1MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

HRM - ORAL AND TRANSDERMAL ESTROGENS AND PROGESTINS

Products Affected

- Cenestin
- Climara Pro
- Combipatch
- Divigel
- Elestrin
- Enjuvia
- Estradiol ORAL TABS
- Estradiol TRANSDERMAL PTTW
- Estradiol TRANSDERMAL PTWK
- Estradiol/norethindrone Acetate
- Estrogel

- Estropipate ORAL TABS
- Jinteli
- Lopreeza
- Menest
- Menostar
- Mimvey
- Mimvey Lo
- Ortho-est
- Prefest
- Premarin ORAL TABS
- Premphase
- Prempro

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

HRM - PLATELET INHIBITORS

Products Affected

• Ticlopidine Hcl

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Requires trial of at least one Non-HRM alternative: clopidogrel, Aggrenox

HRM - SEDATIVE HYPNOTIC AGENTS

Products Affected

- Edluar
- Intermezzo

- Zaleplon
- Zolpidem Tartrate
- Zolpidem Tartrate Er

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) when used longer than 90 days and wishes to proceed with the originally prescribed medication AND intended duration of therapy will be verified.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

HRM - SKELETAL MUSCLE RELAXANTS

Products Affected

- Cyclobenzaprine Hcl ORAL TABS 10MG, 5MG
- Methocarbamol ORAL TABS

- Orphenadrine Citrate INJ
- Orphenadrine Citrate Er

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

HRM - VASODILATORS

Products Affected

• Dipyridamole ORAL TABS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Requires trial of at least one Non-HRM alternative: clopidogrel, Aggrenox

HUMIRA (S)

Products Affected

- Humira
- Humira Pediatric Crohns Disease Starter Pack
- Humira Pen
- Humira Pen-crohns Diseasestarter
- Humira Pen-psoriasis Starter

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis)
Required Medical Information	Diagnosis of one of the following: A) moderate to severe rheumatoid arthritis and inadequate response, intolerance, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., hydroxychloroquine [HCQ], sulfasalazine, methotrexate [MTX], leflunomide, azathioprine, cyclosporine) B) moderate to severe polyarticular juvenile idiopathic arthritis and inadequate response, intolerance or contraindication to one or more non-biologic DMARDs (e.g., HCQ, sulfasalazine, MTX, leflunomide, azathioprine, cyclosporine) C) psoriatic arthritis and inadequate response, intolerance, or contraindication to MTX D) ankylosing spondylitis and inadequate response, intolerance or contraindication to one or more NSAIDs E) moderate to severe chronic plaque psoriasis (affecting more than 5% of body surface area or crucial body areas such as the hands, feet, face, or genitals) and inadequate response, intolerance or contraindication to one or more oral systemic treatments (e.g., MTX, cyclosporine, acitretin, sulfasalazine) F) moderate to severe Crohn's disease and inadequate response, intolerance, or contraindication to two or more of the following: corticosteroids (e.g., prednisone, methylprednisolone) or non-biologic DMARDs (e.g., azathioprine, MTX, mercaptopurine) G) moderate to severe ulcerative colitis and inadequate response, intolerance or contraindication to two or more of the following: corticosteroids (e.g., prednisone, methylprednisolone), 5-ASA (i.e. mesalamine, sulfasalazine, balsalazide, olsalazine) or non-biologic DMARDs (azathioprine, MTX, mercaptopurine).
Age Restrictions	2 years or older for JIA. 6 years or older for CD. 18 years of age or older for all other indications
Prescriber Restrictions	N/A

Coverage Duration	Initial - 16 weeks (CD), 12 weeks (UC), 12 months (others). Renewal - 12 months.
Other Criteria	Patient has been tested for TB and latent TB has been ruled out or is being treated as per guidelines. For renewal, patient has stable disease or has improved while on therapy (For pJIA, reduction in disease flares, improvement in ACR scoring. For RA, improvement in tender/swollen joint count, improvement in ACR scoring. For PsA, improvement in number of swollen/tender joints, pain, stiffness. For AS, improvement in AS symptoms, such as stiffness and back pain. For CD, symptomatic remission. For UC, clinical remission, reduction in steroid use.)

HYSINGLA (BCBS RI)

Products Affected

• Hysingla Er

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Significant respiratory depression. Acute or severe bronchial asthma. Hypercarbia. Known or suspected paralytic ileus.
Required Medical Information	Diagnosis of severe pain requiring continuous around the clock long-term opioid treatment AND Patient has tried and failed or unable to tolerate at least two generic extended-release opioid products, such as: oxymorphone ER, morphine ER, fentanyl, tramadol ER AND Patient is opioid tolerant for 1 week or longer and taking at least: 60mg morphine/day, 25mcg transdermal fentanyl /hour, 30mg of oxycodone daily, 8mg of hydromorphone daily AND Current opioid will be discontinued with the inception of Hysingla ER
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Not covered for members enrolled in a Medicare approved hospice program

IBRANCE (S)

Products Affected

• Ibrance

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of estrogen receptor positive, human epidermal growth factor receptor 2-negative advanced breast cancer and Patient is a postmenopausal woman and Ibrance will be used in combination with letrozole
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ICLUSIG (S)

Products Affected

• Iclusig

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of chronic myelogenous leukemia (CML) and patient has tried and failed, resistance, relapse or contraindication to at least two FDA-approved tyrosine kinase inhibitors OR Diagnosis of CML and the patient has a known T315I mutation OR Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia and the patient has tried and failed, resistance, relapse or contraindication to at least two FDA-approved tyrosine kinase inhibitors.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ILARIS (S)

Products Affected

• Ilaris

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of cryopyrin-associated period syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS) OR Diagnosis of active systemic juvenile idiopathic arthritis (sJIA) AND patient has tried and had an inadequate response, contraindication or intolerance to corticosteroids (e.g., prednisone, methylprednisolone) or methotrexate
Age Restrictions	CAPS - 4 years of age or older. sJIA - 2 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with or recommendation of, an immunologist, allergist, dermatologist, rheumatologist, neurologist, or other medical specialist
Coverage Duration	12 months
Other Criteria	For renewal, patient experienced disease stability or improvement.

IMBRUVICA (S)

Products Affected

• Imbruvica

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of A) mantle cell lymphoma AND patient has relapsed or is refractory to at least one prior therapy for the treatment of MCL, B) chronic lymphocytic leukemia and patient has relapsed or is refractory to at least one prior therapy for the treatment of CLL, or C) Waldenstrom's macroglobulinemia
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

INCRELEX (S)

Products Affected

• Increlex

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Closed epiphyses. Active or suspected malignancy.
Required Medical Information	Diagnosis of growth failure in a child with severe primary IGF-1 deficiency, defined as height standard deviation score (SDS) less than or equal to -3.0 AND basal IGF-1 SDS less than or equal to -3.0 AND normal or elevated growth hormone OR Diagnosis of growth hormone gene deletion with development of neutralizing antibodies to growth hormone AND other causes of IGF-1 deficiency (e.g., hypothyroidism, nutritional deficiencies, pituitary disorders, etc.) have been ruled out or corrected prior to initiating therapy.
Age Restrictions	N/A
Prescriber Restrictions	Pediatric endocrinologist
Coverage Duration	12 months
Other Criteria	For renewal, Patient had a minimum growth rate of at least 2 cm/year.

INLYTA (S)

Products Affected

• Inlyta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of advanced renal cell carcinoma AND patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens)
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

INTRON A (S)

Products Affected

• Intron A W/diluent

• Intron A INJ 10MU, 18MU, 50MU, 6000000UNIT/ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Uncontrolled depression. Solid organ transplant other than liver. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon and ribavirin.
Required Medical Information	Diagnosis of hairy cell leukemia OR Diagnosis of Condylomata acuminata OR Diagnosis of AIDS-related Kaposi's sarcoma OR Clinically aggressive follicular lymphoma and the medication will be used concurrently with anthracycline-containing chemotherapy or is not a candidate for anthracycline-containing chemotherapy OR Malignant melanoma and the request for coverage is within 56 days of surgery and the patient is at high risk of disease recurrence OR Diagnosis of chronic hepatitis B with compensated liver disease and patient has evidence of hepatitis B viral replication and patient has been serum hepatitis B surface antigen-positive for at least 6 months OR Diagnosis of chronic hepatitis C with compensated liver disease and is receiving combination therapy with ribavirin, unless ribavirin is contraindicated, and the medication will not be used as part of triple therapy with a protease inhibitor and patient has a clinical reason for not using peginterferon
Age Restrictions	1 year of age or older for HBV. 3 years of age or older for HCV. 18 years of age or older for other indications.
Prescriber Restrictions	For HCV, hepatologist, gastroenterologist, or infectious disease specialist
Coverage Duration	Condylomata: 3 mos. HBV e antigen pos: 16 wks, e antigen neg: 48 wks. KS: 16 wks. Others: 12 mos
Other Criteria	N/A

INVEGA TRINZA (BCBS RI)

Products Affected

• Invega Trinza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of schizophrenia AND Paliperidone has been established as adequate treatment for at least 4 months AND The last 2 doses of monthly intramuscular (IM) paliperidone is the same dosage strength before starting INVEGA TRINZA
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

IRESSA (S)

Products Affected

• Iressa

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

IVIG (S)

Products Affected

- Bivigam
- Carimune Nanofiltered INJ 6GM
- Flebogamma Dif
- Gammagard Liquid INJ 2.5GM/25ML
- Gammaked

- Gammaplex
- Gamunex-c
- Hizentra
- Octagam
- Privigen INJ 20GM/200ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	History of hypersensitivity (including anaphylaxis or severe systemic reaction) to immune globulin or any component of the preparation. Privigen only: hyperprolinemia. Octagam only: allergy to corn.
Required Medical Information	Medication will be given intravenously and the patient has one of the following: A) idiopathic thrombocytopenic purpura (ITP) after trial of corticosteroids unless the platelet count is less than 30,000 cells/mm3, B) Kawasaki syndrome, C) hypogammaglobulinemia (Ig level less than 500 mg/dL) and recurrent bacterial infection associated with B-cell chronic lymphocytic leukemia, D) chronic inflammatory demyelinating polyneuropathy (CIDP), E) multifocal motor neuropathy (MMN). OR Medication will be given by the subcutaneous route or intravenous route and patient has a diagnosis of one of the following types of primary immunodeficiency (PI): hypogammaglobulinemia, severe combined immunodeficiency, X-linked immunodeficiency with hyperimmunoglobulin M, congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, Hyperimmunoglobulinemia E syndrome, selective antibody deficiency. For IV administration only: Patient will not take the medication at the minimum concentration available and the minimum infusion rate practicable if they have one of the following conditions: Pre-existing renal insufficiency, diabetes mellitus, volume depletion, sepsis, paraproteinemia, age over 65 years, receiving known nephrotoxic drugs.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ITP, Kawasaki - 3 months, Other - 12 months.

Other Criteria	Part B: Patient has a diagnosis of primary immune deficiency and the medication will be provided in the home. Part D: Medication will be given in the home and the patient has a diagnosis other than PID OR the
	medication will not be given in the home.

JAKAFI (S)

Products Affected

Jakafi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of : A) myelofibrosis (primary, post-poycythemia vera or post-essential thrombocythemia) AND patient has two or more of the following: age older than 65 years, white blood cell count greater than 25 x 109/L, hemoglobin less than 10 g/dL, peripheral blasts more than 1%, constitutional symptoms (e.g., night sweats, fevers, unintentional weight loss, debilitating fatigue), B) polycythemia vera AND Patient has a contraindication, intolerance or inadequate response to hydroxyurea
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	For renewal, the patient experienced one of the following: At least 35% reduction in spleen volume from baseline as measured by CT or MRI or a 50% reduction in spleen size from baseline based on palpation OR 2 g/dL or greater increase in hemoglobin level (in transfusion-indpendent) or becoming transfusion independent (for transfusion dependent) OR Improvement in symptoms (i.e. abdominal discomfort, pain under left ribs, early satiety, night sweats, itching, bone or muscle pain) withour progressive splenomegaly or worsening of anemia (i.e. newly transfusion dependent or hemoglobin reduction by 2 g/dL that persists for at least 12 weeks), thrombocytopenia (more than 2-grade decline but above 25,000 x 109/L) or neutropenia (more than 2-grade decline but above 0.5 x 109/L)

JUXTAPID (S)

Products Affected

• Juxtapid

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests. Pregnancy. Concomitant use with strong or moderate CYP3A4 inhibitors.
Required Medical Information	Diagnosis of homozygous familial hypercholesterolemia as evidenced by one of the following: A) genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or autosomal recessive hypercholesterolemia (ARH) adaptor protein gene locus OR B) untreated/pre-treatment LDL greater than 500 mg/dL with at least one of the following: cutaneous or tendonous xanthoma before age 10 years, history of early vascular disease (men younger than 55 years, women younger than 60 years) on both sides fo the family if parenteral LDL levels are unknown, elevated LDL cholesterol levels before lipid-lowering therapy consistent with heterozygous FH in both parents where LDL levels are known: LDL cholesterol more than 250 mg/dL in a patient 30 years of age or older, LDL cholesterol greater than 220 mg/dL for patients 20 to 29 years of age, LDL cholesterol greater than 190 mg/dL in patients younger than 20 years AND Medication will be used as adjunct to a lowfat diet and other lipid-lowering treatments AND Patient has tried and had an inadequate response to the maximum tolerated dose of a high potency statin (e.g., atorvastatin, rosuvastatin), unless all statin are contraindicated
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial - 6 months. Renewal - 12 months
Other Criteria	For renewal, patient has responded to therapy with a decrease in LDL levels from baseline AND patient does not have contraindications to therapy.

KALYDECO (S)

Products Affected

• Kalydeco

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of cystic fibrosis AND Patient has one of the following mutations: G551D, G1244E, G1349D, G178R, G551S, R117H, S1251N, S1255P, S549N, or S549R on at least one allele in the cystic fibrosis transmembrane conductance regulator gene documented by an FDA-cleared cystic fibrosis-mutation test and followed by verification with bidirectional sequencing when recommended by the mutation test instructions
Age Restrictions	Ivacaftor oral granules: 2 years of age or older Ivacaftor oral tablets: 6 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient has experienced benefit from therapy (i.e. improvement in pulmonary lung function [FEV1], decreased number of pulmonary exacerbations)

KANUMA (S)

Products Affected

• Kanuma

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of lysosomal acid lipase deficiency (LAL-D) AND Diagnosis was confirmed by an enzymatic blood (e.g., dried blood spot test) or genetic test
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism
Coverage Duration	12 months
Other Criteria	N/A

KEVEYIS (S)

Products Affected

• Keveyis

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Hepatic deficiency (Child-Pugh Class A), Severe pulmonary disease (e.g., severe COPD) Concomitant high dose aspirin (greater than 100 mg/day).
Required Medical Information	Diagnosis of one of the following: A) primary hyperkalemia peirodic paralysis, B) primary hypokalemic periodic paralysis, or C) paramyotonia Congenita with periodic paralysis
Age Restrictions	N/A
Prescriber Restrictions	Neurologist
Coverage Duration	Initial - 3 months. Renewal - 12 months
Other Criteria	For renewal, documentation of positive clinical response.

KEYTRUDA (S)

Products Affected

• Keytruda

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The patient has a diagnosis of metastatic melanoma AND the patient has experienced disease progression following therapy with Yervoy AND if the patient is positive for a BRAF V600E or V600K mutation, the pateint has experienced disease progression following therapy with one of the following: Zelboraf, Tafinlar, Mekinist
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

KINERET (BCBS RI)

Products Affected

• Kineret

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis)Concomitant use with TNF or Orencia. CHF. Hepatitis B infection
Required Medical Information	Diagnosis of moderate to severe rheumatoid arthritis and patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs) for at least 3 consecutive months and tiral and failure with Enbrel, Humira, Remicade OR Diagnosis of cryopyrin-associated periodic syndrome (CAPS) with neonatal-onset multisystem inflammatory disease (NOMID)
Age Restrictions	N/A
Prescriber Restrictions	For CAPS, diagnosed by, or upon consultation with or recommendation of, an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist
Coverage Duration	12 months
Other Criteria	Patient has been tested for TB in the past year and latent TB has been ruled out or is being treated per guidelines. Dosing as per the FDA labeling for rheumatoid arthritis. For renewal, patient has stable disease or improved on treatment (For RA, improvement in tender/swollen joint count, improvement in ACR scoring. For CAPS, symptom improvement, improvement in serum markers of inflammation)

KORLYM (S)

Products Affected

• Korlym

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy. Patient requires concomitant treatment with long-term corticosteroids (e.g., immunosuppression for organ transplant). History of unexplained vaginal bleeding. Endometrial hyperplasia with atypia or endometrial carcinoma. Concomitantly taking simvastatin, lovastatin, or a CYP3A substrate with a narrow therapeutic index (e.g., cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, or tacrolimus)
Required Medical Information	Diagnosis of endogenous Cushing's syndrome AND diagnosis of type 2 diabetes mellitus or glucose intolerance AND Patient has hyperglycemia secondary to hypercortisolism AND patient has failed or is not a candidate for surgery
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, Patient had a positive response to therapy with Korlym

KUVAN (S)

Products Affected

• Kuvan

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of phenylketonuria (PKU) and patient is and will be maintained on a phenylalanine-restricted diet
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 2 months. Renewal: 12 months.
Other Criteria	For initial approval, Patient will have phenylalanine levels measured one week after starting therapy and periodically for up to two months of therapy to determine response. For renewal, patient has been determined to be a responder to therapy (i.e. phenylalanine levels have decreased by at least 30% from baseline) and phenylalanine levels will be measured periodically during therapy.

KYNAMRO (S)

Products Affected

• Kynamro

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests.
Required Medical Information	Diagnosis of homozygous familial hypercholesterolemia as evidenced by one of the following: A) genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or autosomal recessive hypercholesterolemia (ARH) adaptor protein gene locus OR B) untreated/pre-treatment LDL greater than 500 mg/dL with at least one of the following: cutaneous or tendonous xanthoma before age 10 years, history of early vascular disease (men younger than 55 years, women younger than 60 years) on both sides of the family if parenteral LDL levels are unknown, elevated LDL cholesterol levels before lipid-lowering therapy consistent with heterozygous FH in both parents AND Medication will be used as adjunct to a low-fat diet and other lipid-lowering treatments AND Patient has tried and had an inadequate response to the maximum tolerated dose of a high potency statin (e.g., atorvastatin, rosuvastatin), unless all statin are contraindicated
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial - 6 months. Renewal - 12 months
Other Criteria	For renewal, patient has responded to therapy with a decrease in LDL levels from baseline AND patient does not have contraindications to therapy.

LEMTRADA (BCBS RI)

Products Affected

• Lemtrada

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	HIV infection. Active or latent TB. Active infections. Concurrent antineoplastic/immunosuppressive therapy. History of PML.
Required Medical Information	Diagnosis of relapsing multiple sclerosis AND Clinical failure for efficacy (defined as relapse or increased active MRI lesions) to an interferon beta product and at least one agent in a different MS class AND Clinical failure will be confirmed with evidence of medication adherence to treatment by pharmacist via claims data AND Lemtrada will be used as monotherapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Total duration of therapy: 24 months lifetime
Other Criteria	Dosing: 12mg daily for 5 days (total of 60mg), 12 months later: 12mg daily for 3 days (total of 36mg). Premedicate with corticosteroids for initial 3 days of therapy (1 gm of methylprednisolone).

LENVIMA (S)

Products Affected

- Lenvima 10mg Daily Dose
- Lenvima 14mg Daily Dose
- Lenvima 18mg Daily Dose

- Lenvima 20mg Daily Dose
- Lenvima 24mg Daily Dose
- Lenvima 8mg Daily Dose

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of locally recurrent or metastatic, progressive differentiated thyroid cancer AND the cancer is refractory to radioactive iodine treatment
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

LETAIRIS (S)

Products Affected

• Letairis

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of pulmonary arterial hypertension WHO Group I with New York Heart Association (NYHA) with functional class II or III that was confirmed by right heart catheterization AND female patients have been enrolled in the Letairis REMS program.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial - 6 months. Renewal - 12 months
Other Criteria	N/A

LEUKINE (S)

Products Affected

• Leukine INJ 250MCG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Excessive leukemic myeloid blasts (10% or higher) in bone marrow/peripheral blood. Simultaneous use with cytotoxic chemotherapy or radiotherapy.
Required Medical Information	A) malignant melanoma, B) Adjunct therapy (tx) for severe febrile neutropenia (FN) and receiving myelosuppressive tx for non-myeloid malignancy and one: Received prophylactic CSF (not Neulasta) OR Did not receive prophylactic CSF and used as adjunct to antibiotics in highrisk pt with any one: 65 years or older, Pneumonia, Hypotension and multiorgan dysfunction (sepsis syndrome), Invasive fungal infection or clinically-documented infection, Hospitalized when fever developed, Prior FN, Severe (ANC less than 100/mcL) or anticipated prolonged (more than 10 days) neutropenia, C) Autologous peripheral-blood progenitor cell transplant for collection by leukapheresis, D) Myeloablative chemotx for non-myeloid malignancy followed by BMT, E) Acute myeloid leukemia after completing induction/consolidation chemotx, F) Acute lymphoblastic leukemia after completing first few days of chemotx of initial induction or first post-remission course, G) Myelodysplastic syndrome with severe neutropenia and recurrent infection, H) Receiving radiation tx, not chemotx, and expect prolonged tx delays due to neutropenia, I) Neutropenia due to HIV infection and antiretroviral tx, J) Aplastic anemia, K) Primary prophylaxis of FN and one: at least 20% FN risk based on chemotx OR 10% up to 20% risk with one of the following: 65 years or older, Poor performance status, Poor nutritional status, Previous FN, Extensive prior tx with large radiation ports, Cytopenias due to bone marrow involvement by tumor, Receiving combined chemoradiotx, Open wounds or active infections, Other serious comorbidity (e.g., renal or liver dysfunction) OR less than 10% risk and intent is curative or adjuvant and at risk for serious medical consequences, including death L) Myelosuppressive chemotx for non-myeloid malignancy. M) Secondary prophylaxis of FN in pt with neutropenic complication from prior chemotx cycle (where primary prophylaxis was not given) N) Allogeneic or autologous bone marrow transplant
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

LIDODERM (S)

Products Affected

• Lidocaine PTCH

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of post-herpetic neuralgia
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

LINZESS (S)

Products Affected

• Linzess

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Mechanical gastrointestinal obstruction.
Required Medical Information	Diagnosis of irritable bowel syndrome-constipation for at least 12 non-consecutive weeks and patient has tried and failed increasing fluid and fiber intake and patient has tried and failed or has an intolerance to osmotic laxatives, stimulant laxatives or probiotics OR Diagnosis of chronic idiopathic constipation for at least 3 months and patient has tried and failed increasing fluid and fiber intake and patient has tried and failed or has an intolerance to osmotic laxatives, stimulant laxatives or stool softeners.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Initial - 4 months. Renewal - 12 months
Other Criteria	For renewal, the patient has experienced an increase in the number of bowel movements.

LONSURF (S)

Products Affected

• Lonsurf

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of metastatic colorectal cancer AND history of failure, contraindication, or intolerance to at least one component in the following: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND history of failure, contraindication, or intolerance to at least one anti-VEGF therapy (e.g., Avastin) AND One of the following: A) patient has KRAS wild-type tumors and history of failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR Patient has KRAS mutant tumors
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an oncologist
Coverage Duration	12 months
Other Criteria	N/A

LUMIZYME (S)

Products Affected

• Lumizyme

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Pompe disease (GAA) deficiency
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

LUPANETA (S)

Products Affected

• Lupaneta Pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Undiagnosed abnormal uterine bleeding. Breastfeeding. Known, suspected or history of breast cancer or other hormone-sensitive cancer. Thrombotic or thromboembolic disorders. Liver tumors or liver disease.
Required Medical Information	Diagnosis of endometriosis And patient is undergoing an initial treatment course and has had an inadequate pain control response, intolerance or contraindication to one of the following: Danazol, Combination [estrogen/progesterone] oral contraceptives, Progestins OR Patient is undergoing a recurrent treatment course and is experiencing a reappearance of symptoms after an initial course of leuprolide therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	In patients of child-bearing potential, pregnancy has been excluded and patient will use non-hormonal contraception during and for 12 weeks afer therapy.

LUPRON DEPOT (S)

Products Affected

• Leuprolide Acetate INJ

• Lupron Depot INJ 22.5MG, 3.75MG, 30MG, 45MG, 7.5MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy in patients with child-bearing potential. Breastfeeding. Undiagnosed abnormal vaginal bleeding.
Required Medical Information	Diagnosis of one of the following: A) advanced or metastatic prostate cancer (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), B) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only) and for initial, patient has had an inadequate pain control response or patient has an intolerance or contraindication to one of the following: Danazol OR Combination [estrogen/progesterone] Oral Contraceptives OR Progestins and for retreatment course, Patient is experiencing recurrence of symptoms after an initial course of therapy with leuprolide acetate and Norethindrone acetate 5 mg daily will be coadministered, or C) Anemia due to uterine Leiomyomata (Fibroids) (3.75 mg 1-month &11.25 mg 3-month depots only) and Patient is preoperative and Patient has tried and had an inadequate response to monotherapy with iron and Patient will be receiving concomitant iron therapy while on leuprolide.
Age Restrictions	Uterine fibroids - 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Endometriosis - 6 months, Uterine fibroids - 3 months, Prostate cancer - 12 months.
Other Criteria	For endometriosis and uterine fibroids, patient will be using nonhormonal contraception during and for 12 weeks after therapy.

LUPRON DEPOT- PED (S)

Products Affected

• Lupron Depot INJ 11.25MG

• Lupron Depot-ped

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of central precocious puberty and patient had early onset of secondary sexual characteristics (male: earlier than 9 years of age. female: earlier than 8 years of age) and advanced bone age of at least one year compared with chronological age and has undergone gonadotropin-releasing hormone agonist (GnRHa) testing with peak luteinizing hormone (LH) level above pre-pubertal range or random LH level in pubertal range and Patient had the following diagnostic evaluations to rule out tumors, when suspected: diagnostic imaging of the brain (MRI or CT scan), Pelvic/testicular/adrenal ultrasound (if steroid levels suggest suspicion), Human chorionic gonadotropin levels (in all boys), Adrenal steroids to rule out congenital adrenal hyperplasia
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pediatric endocrinologist
Coverage Duration	12 months
Other Criteria	For renewal of CPP, LH levels have been suppressed to pre-pubertal levels and consideration for discontinuation of therapy when the patient is 11 years of age for girls and 12 years of age for boys.

LYNPARZA (S)

Products Affected

• Lynparza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The patient has a diagnosis of advanced ovarian cancer AND The patient has a deleterious or suspected deleterious germline BRCA mutation, confirmed by an FDA approved test AND LYNPARZA will be used as monotherapy AND The patient has had a trial and inadequate response or intolerance to three or more prior chemotherapy regimens.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

MEKINIST (S)

Products Affected

• Mekinist

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of unresectable or metastatic melanoma and medication is used as a single agent and patient has a positive BRAF V600E or V600K mutation as detected by an FDA-approved test (THxID-BRAF Kit) or Clinical Laboratory Improvement Amendments (CLIA)-approved facility, and the patient has not received prior BRAF-inhibitor therapy OR medication will be used in combination with Tafinlar in a patient with BRAF V600E or V600K mutations, as detected by an FDA-approved test (THxID-BRAF kit) or Clinical Laboratory Improvement Amendments (CLIA)-approved facility.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

MODAFINIL (S)

Products Affected

Modafinil

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following: A) excessive sleepiness associated with obstructive sleep apnea (OSA)/hypopnea syndrome confirmed by sleep lab evaluation (e.g., multiple sleep latency test, polysomnography) and documentation of residual excessive sleepiness B) excessive sleepiness associated with narcolepsy confirmed by sleep lab evaluation (e.g., multiple sleep latency test, polysomnography) and patient has tried and failed, is unable to tolerate, or has contraindication(s) to at least one other central nervous system stimulant (e.g., methylphenidate, mixed amphetamine salts, dextroamphetamine) OR Diagnosis of excessive sleepiness associated with shift work disorder confirmed by sleep lab evaluation (e.g., multiple sleep latency test, polysomnography) and sleep disturbance causes measurable functional impairment in social, occupational, or other important areas of functioning that has persisted for at least three months.
Age Restrictions	16 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	OSA/hypopnea syndrome - 6 months (initial), 12 months (renewal). Other diagnoses - 12 months.
Other Criteria	N/A

Mozobil (s)

Products Affected

• Mozobil

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient is to undergo autologous stem cell transplantation for the treatment of non-Hodgkin's lymphoma or multiple myeloma AND Patient will concomitantly receive a daily dose of a granulocyte colonystimulating factor (G-CSF) for 4 days prior to the first evening dose of Mozobil and on each day prior to apheresis while using Mozobil.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	4 days
Other Criteria	N/A

MS INTERFERONS (BCBS RI)

Products Affected

- Avonex
- Avonex Pen
- Plegridy
- Plegridy Starter Pack

- Rebif
- Rebif Rebidose
- Rebif Rebidose Titration Pack
- Rebif Titration Pack

PA Criteria	Criteria Details
Covered Uses	All-FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of relapsing form of multiple sclerosis OR diagnosis of first clinical episode and MRI features consistent with multiple sclerosis. For Extavia only: Patient has experienced intolerance to therapy with BETASERON.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient has experienced an objective response to therapy (i.e. no or slowed progression of disease)

MYALEPT (BCBS RI)

Products Affected

• Myalept

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of congenital or acquired generalized lipodystrophy AND patient has one or more of the following metabolic abnormalities: insulin resistance (defined as requiring more than 200 units per day), hypertriglyceridemia, or diabetes AND patient is refractory to current standards of care for lipid and diabetic management AND the prescriber is registered in the MYALEPT REMS program
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	Renewal: sustained reduction in hemoglobin A1C level from baseline of 0.5% or sustained reduction in fasting triglyceride levels tp less than 200mg/dl or 40% from baseline

MYOZYME (S)

Products Affected

• Myozyme

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of infantile-onset Pompe disease (GAA) deficiency.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

NAGLAZYME (S)

Products Affected

• Naglazyme

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Mucopolysaccharidosis VI (MPS VI or Maroteaux-Lamy syndrome).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

NATPARA (S)

Products Affected

• Natpara

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of hypocalcemia due to chronic hypoparathyroidism AND NATPARA is not being used in the setting of acute post-surgical hypoparathyroidism AND Patient does not have a known calcium-sensing receptor mutation AND Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months AND Patient has been optimized on adequate doses of oral calcium (more than 1,000 mg daily) and vitamin D (calcitriol greater than or equal to 0.25 μg/day) or alfacalcidol greater than or equal to 0.50 μg/day) supplementation AND Patient has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy (or if on therapy, the dose had to have been stable for 3 months or longer) AND Patient has normal magnesium and serum 25-hydroxyvitamin D concentrations AND Creatinine clearance is at least 30 mL/min on two separate measurements, or greater than 60 mL/min (one measurement) with an accompanying serum creatinine concentration of less than 1.5 mg/dL AND NATPARA will be used as an adjunct to calcium and vitamin D AND Prescriber is certified in the NATPARA REMS program
Age Restrictions	N/A
Prescriber Restrictions	endocrinologist
Coverage Duration	initial: 4 months, renewal - 12 months
Other Criteria	For renewal, Patient has achieved and maintained serum calcium levels in the normal range (8 – 10.6 mg/dL) or experienced a 50% or greater reduction in oral calcium intake or 50% or greater reduction in oral vitamin D intake AND Prescriber is certified in the NATPARA REMS program.

NEULASTA (S)

Products Affected

• Neulasta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	For use as primary prophylaxis of febrile neutropenia (FN) in one of the following patients: A) Patient has a 20% or higher risk of FN based on chemotherapy regimen OR B) Patient has 10% to less than 20% risk of developing FN based on chemotherapy regimen AND at least one of the following risk factors are present: 65 years or older, Poor performance status, Poor nutritional status, Previous episodes of febrile neutropenia, Extensive prior treatment including large radiation ports, Cytopenias due to bone marrow involvement by tumor, Administration of combined chemoradiotherapy, Presence of open wounds or active infections, Other serious comorbidities (including renal or liver dysfunction notably elevated bilirubin), or C) patient has less than 10% risk of developing FN based on chemotherapy regimen AND the intent of treatment is curative or adjuvant and patient is at risk for serious medical consequences of FN, including death and patient is receiving myelosuppressive chemotherapy regimen for a non-myeloid malignancy, or D) For use as secondary prophylaxis of FN in a patient who had a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

NEUMEGA (S)

Products Affected

• Neumega

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Patient has undergone myeloablative chemotherapy.
Required Medical Information	Diagnosis of non-myeloid malignancy and patient has undergone myelosuppressive chemotherapy (placing them at high risk for thrombocytopenia)
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

NEUPOGEN (S)

Products Affected

• Neupogen

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	A) congenital, cyclic, or idiopathic neutropenia, B) Adjunct therapy (tx) for severe febrile neutropenia (FN) and receiving myelosuppressive tx for non-myeloid malignancy with any one: Received prophylactic CSF (not Neulasta) OR Did not receive prophylactic CSF and Use as adjunct to antibiotics in high-risk pt and any one: 65 years or older, Pneumonia, Hypotension and multiorgan dysfunction (sepsis syndrome), Invasive fungal infection or clinically-documented infection, Hospitalized when developed fever, Prior FN, Severe (ANC less than 100/mcL) or anticipated prolonged (more than 10 days) neutropenia, C) Autologous peripheral-blood progenitor cell transplant for collection by leukapheresis, D) Myeloablative chemotx for non-myeloid malignancy followed by BMT, E) Acute myeloid leukemia after completing induction/consolidation chemotx, F) Acute lymphoblastic leukemia after completing first few days of chemotx of initial induction or first post-remission course, G) Myelodysplastic syndrome with severe neutropenia and recurrent infection, H) Receiving radiation tx, not chemotx, and expect prolonged tx delays due to neutropenia, I) Neutropenia due to HIV infection and antiretroviral tx, J) Aplastic anemia, K) Primary prophylaxis of FN in one of the following: at least 20% FN risk based on chemotx OR 10% up to 20% risk with one of the following: 65 years or older, Poor performance status, Poor nutritional status, Previous FN, Extensive prior tx with large radiation ports, Cytopenias due to bone marrow involvement by tumor, Combined chemoradiotx, Open wounds or active infections, Other serious comorbidities (e.g., renal or liver dysfunction) OR less than 10% risk and intent is curative or adjuvant and risk for serious medical consequences, including death L) Receiving myelosuppressive chemotx for non-myeloid malignancy M) Secondary prophylaxis of FN in pt with neutropenic complication from prior chemotx cycle (where primary prophylaxis was not received)
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	12 months
Other Criteria	N/A

NEXAVAR (S)

Products Affected

• Nexavar

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	squamous cell lung cancer being treated with carboplatin and paclitaxel.
Required Medical Information	Diagnosis of one of the following: A) unresectable hepatocellular carcinoma, B) Advanced renal cell carcinoma C) locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

NINLARO (S)

Products Affected

• Ninlaro

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with Revlimid (lenalidomide) and dexamethasone.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy. Multiple myeloma: Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)].

NORTHERA (S)

Products Affected

• Northera

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of neurogenic orthostatic hypertension (NOH) AND NOH is due to one of the following: primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy AND Patient has symptoms of NOH: Orthostatic dizziness, Lightheadedness, "feeling that you are about to black out" AND Patient has tried and had an inadequate response, contraindication or intolerance to midodrine
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	For renewal, Patient does not have persistent or sustained supine hypertension (SBP more than 180 mmHg or DBP more than 110 mmHg), Patient does not have persistent or sustained standing or sitting hypertension (SBP more than 180 mmHg or DBP more than 110 mmHg), and Patient had improvement in symptoms of NOH. Sustained mean elevated blood pressure that persists for longer than 5 minutes after change in position. Persistent means elevated BP that occurs on more than one occasion on separate physician office visits

NOXAFIL (S)

Products Affected

• Noxafil

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitant treatment with sirolimus, CYP 3A4 substrates (pimozide, quinidine), HMG-CoA Reductase inhibitors primarily metabolized through CYP 3A4, or ergot alkaloids
Required Medical Information	Diagnosis of oropharyngeal candidiasis and patient tried and failed itraconazole and/or fluconazole OR Medication will be used as prophylaxis of invasive Aspergillus and Candida infections and the patient is at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.
Age Restrictions	13 years of age or older for prophylaxis of invasive Aspergillus or Candidate infection
Prescriber Restrictions	N/A
Coverage Duration	12 weeks
Other Criteria	N/A

NPLATE (S)

Products Affected

• Nplate

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of relapsed/refractory chronic immune (idiopathic) thrombocytopenic purpura (ITP) for greater than 6 months AND Baseline platelet count is less than 50,000/mcL AND Degree of thrombocytopenia and clinical condition increase the risk of bleeding AND Patient had an insufficient response, intolerance, contraindication to corticosteroids or immune globulin or inadequate response or contraindication to splenectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, after at least 4 weeks of therapy at the maximum weekly dose (10 mcg/kg) the platelet count increased to a sufficient level to avoid clinically important bleeding.

NUPLAZID (S)

Products Affected

• Nuplazid

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Nuvigil (s)

Products Affected

• Armodafinil

• Nuvigil

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following: A) excessive sleepiness associated with obstructive sleep apnea (OSA)/hypopnea syndrome confirmed by sleep lab evaluation (e.g., multiple sleep latency test, polysomnography) and documentation of residual excessive sleepiness B) excessive sleepiness associated with narcolepsy confirmed by sleep lab evaluation (e.g., multiple sleep latency test, polysomnography) and patient has tried and failed, is unable to tolerate, or has contraindication(s) to at least one other central nervous system stimulant (e.g., methylphenidate, mixed amphetamine salts, dextroamphetamine) OR Diagnosis of excessive sleepiness associated with shift work disorder confirmed by sleep lab evaluation (e.g., multiple sleep latency test, polysomnography) and sleep disturbance causes measurable functional impairment in social, occupational, or other important areas of functioning that has persisted for at least three months.
Age Restrictions	17 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	OSA/hypopnea syndrome - 6 months (initial), 12 months (renewal). Other diagnoses - 12 months.
Other Criteria	N/A

ODOMZO (S)

Products Affected

• Odomzo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of locally advanced basal cell carcinoma and one of the following: A) cancer has recurred following surgery or radiation therapy or B) patient is not a candidate for surgery or radiation therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a dermatologist or oncologist
Coverage Duration	12 months
Other Criteria	N/A

OFEV (S)

Products Affected

• Ofev

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The patient has a diagnosis of idiopathic pulmonary fibrosis confirmed by a high resolution CT scan or biopsy AND the patient does not have evidence or suspicion of an alternative interstitial lung disease diagnosis AND liver function tests have been performed prior to start of therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	For renewal, patient experienced stabilization from baseline or a less than 10 percent decline in force vital capacity AND the patient has not experienced AST or ALT elevations greater than 5 times the upper limit of normal or greater than 3 times the upper limit of normal with signs or symptoms of severe liver damage.

OLYSIO (BCBS RI)

Products Affected

• Olysio

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Patient has not previously failed a treatment regimen with a hepatitis C protease inhibitor AND Diagnosis of chronic hepatitis C genotype 1 virus infection with compensated liver disease AND A) medication will be used with ribavirin and peginterferon alfa AND patients with genotype 1a HCV infection have been screened for NS3 Q80K polymorphism and the patient does not have the polymorphism or B) medication will be used in combination with Sovaldi in patients who are either treatment naïve or treatment experienced who have failed PEG-IFN and RBV genotype 1 are eligible
Age Restrictions	N/A
Prescriber Restrictions	Medication is prescribed or in consultation with gatroenterologist, hepatologist or infection disease specialist
Coverage Duration	12wks. 24wks: with SOF and G1a neg for Q80K and G1b, with cirrhosis (tx naive or failed PEG-IFN/RBV)
Other Criteria	N/A

OPDIVO (S)

Products Affected

• Opdivo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The patient has a diagnosis of metastatic melanoma AND the patient has experienced disease progression following therapy with Yervoy AND if the patient is positive for a BRAF V600 mutation, the patient has experienced disease progression following therapy with one of the following: Zelboraf, Tafinlar, Mekinist OR a diagnosis of metastatic squamous non-small cell lung cancer AND patient has experienced progression on or after platinum-based chemotherapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

OPSUMIT (S)

Products Affected

• Opsumit

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy.
Required Medical Information	Diagnosis of pulmonary arterial hypertension WHO group I with New York Heart Association Functional Class II or III AND diagnosis was confirmed by right heart catheterization AND female patients are enrolled in the OPSUMIT REMS program
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months - initial. 12 months - renewal
Other Criteria	For renewal, medication was effective (i.e. improved 6 minute walk distance, oxygen saturation, etc.)

ORENCIA (BCBS RI)

Products Affected

• Orencia

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Active serious infection (including tuberculosis)
Required Medical Information	Diagnosis of moderate to severe rheumatoid arthritis and patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs) for at least 3 consecutive months AND has tried, failed or has a contraindication to Enbrel or Humira OR Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis and patient had an inadequate response, intolerance or contraindication to one or more non-biologic DMARDs for at least 3 consecutive months and patient had an inadequate response to one or more tumor necrosis factor inhibitors Enbrel or Humira
Age Restrictions	6 years of age or older for JIA. 18 years of age or older for rheumatoid arthritis
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has been tested for TB and latent TB has been ruled out or is being treated. Dosing as per FDA approved labeling. For renewal, patient has stable disease or has improved while on therapy (e.g., for pJIA, reduction in disease flares, improvement in ACR scoring. For RA, improvement in tender/swollen joint count, improvement in ACR scoring.)

ORENITRAM (S)

Products Affected

• Orenitram

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	severe hepatic impairment (Child Pugh Class C)
Required Medical Information	Diagnosis of pulmonary arterial hypertension WHO Group I with New York Heart Association (NYHA) functional class III or III that was confirmed by right heart catheterization
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months - initial. 12 months - renewal
Other Criteria	N/A

ORKAMBI (S)

Products Affected

• Orkambi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of cystic fibrosis (CF) AND Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene AND The presence of the mutation was documented by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments-approved facility.
Age Restrictions	12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

OTEZLA (R)

Products Affected

• Otezla

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of one of the following: A) psoriatic arthritis AND patient has tried and had an inadequate response, contraindication, or intolerance to HUMIRA and CIMZIA, B) Moderate to severe plaque psoriasis (affecting more than 5% of body surface area or affecting crucial body areas such as the hands, feet, face or genitals) and patient has tried and had an inadequate response, is intolerant of, or is contraindicated to HUMIRA and CIMZIA.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal of psoriatic arthritis, patient has stable disease or has improved on therapy, such as improvement in number of swollen/tender joints, pain, or stiffness.

OXANDRIN (S)

Products Affected

• Oxandrolone ORAL TABS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Breast or prostate cancer in men. Breast cancer in women with hypercalcemia. Pregnancy. Nephrosis or nephrotic phase of nephritis. Hypercalcemia.
Required Medical Information	Patient is receiving treatment as an adjunct therapy to promote weight gain and has one of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons and Patient has had an inadequate response, intolerance, or contraindication to nutritional supplements and a nutritional consult was performed OR Oxandrin (oxandrolone) will be used to counterbalance protein catabolism associated with chronic corticosteroid administration OR Patient has bone pain associated with osteoporosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Osteoporosis bone pain: 1 month. Other diagnoses: 3 months
Other Criteria	For renewal, patient has experienced an objective improvement (i.e. weight gain, increase in lead body mass, or reduction in muscle pain/weakness)

OXYCONTIN (S)

Products Affected

• Oxycodone Hcl Er

• Oxycontin ORAL T12A 15MG, 30MG, 60MG, 80MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Significant respiratory depression. Acute or severe bronchial asthma. Known or suspected paralytic ileus. GI obstruction
Required Medical Information	Diagnosis of severe pain requiring continuous, around-the-clock opioid analgesic for an extended period of time AND patient has tried and failed or unable to tolerate at least two generic extended-release opioid products, such as: oxymorphone ER, morphine ER, fentanyl, methadone, tramadol ER AND Patient is opioid tolerant (for 60-80mg only), taking at least 60 mg oral morphine per day, 25 µg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, or an equianalgesic dose of another opioid for a week or longer
Age Restrictions	11 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

PEGASYS (S)

Products Affected

• Pegasys

• Pegasys Proclick

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Uncontrolled depression. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon and ribavirin.
Required Medical Information	Diagnosis of hepatitis C with compensated liver disease OR Diagnosis of chronic hepatitis B and evidence of hepatitis B viral replication and patient has been serum hepatitis B surface antigen (HBsAg)-positive for at least 6 months.
Age Restrictions	5 years of age or older
Prescriber Restrictions	hepatologist, gastroenterologist, or infectious disease specialist
Coverage Duration	HBV: 12 mos. HCV: Sovaldi, Olysio- 12 wks. Others-16 wks (initial) Renewal- based on FDA label.
Other Criteria	For renewal of HCV, approval is based on the requirements outlined in the FDA-approved labeling, including viral load, presence of cirrhosis, and response to prior therapy.

PEGINTRON (S)

Products Affected

• Pegintron

- Peg-intron Redipen
- Peg-intron Redipen Pak 4

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Uncontrolled depression. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon and ribavirin.
Required Medical Information	Diagnosis of hepatitis C with compensated liver disease
Age Restrictions	3 years of age or older
Prescriber Restrictions	hepatologist, gastroenterologist, or infectious disease specialist
Coverage Duration	Sovaldi, Olysio- 12 wks. Others-16 wks (initial) Renewal- based on FDA label.
Other Criteria	For renewal, approval is based on the requirements outlined in the FDA-approved labeling, including viral load, combination therapy, and response to prior therapy.

PENNSAID (S)

Products Affected

• Pennsaid SOLN 2%

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Previously experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Use for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
Required Medical Information	Patient has a diagnosis of osteoarthritis of the knees AND patient had experienced treatment failure with at least 2 prescription strength oral NSAIDs or patient has a documented swallowing disorder OR has a history of peptic ulcer disease/gastrointestinal bleeding OR patient is more than 65 years of age with one additional risk factor for gastrointestinal adverse event (e.g., use of anticoagulants or chronic corticosteroids)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

POMALYST (S)

Products Affected

• Pomalyst

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of multiple myeloma and the patient has received two prior therapies, including Revlimid and Velcade unless the patient has a contraindication or intolerance to Revlimid or Velcade and the patient has demonstrated disease progression on or within 60 days of completion of last therapy AND the prescriber is registered, and patient is enrolled in the Pomalyst REMS program
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 month
Other Criteria	N/A

PRALUENT (S)

Products Affected

• Praluent

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following: A) heterozygous familial hypercholesterolemia (HeFH) confirmed by: a) Genetic confirmation of a mutation in the LDL receptor, ApoB, or PCSK9, or b) Presence of tendinous xanthomas in patient or first- or second- degree relative with untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, or c) documented assessment of patient using Dutch Lipid Clinic Network diagnostic criteria with a cumulative score greater than or equal to 9 points, B) clinical atherosclerotic cardiovascular disease (defined as ACS, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin) and requires additional lowering of LDL-C AND medication will not be used with another PCSK9 inhibitor, Kynamro, or Juxtapid AND One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: LDL-C greater than or equal to 100 mg/dL with ASCVD or equivalent cardiovascular risk or LDL-C greater than or equal to 130 mg/dL without ASCVD.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a cardiologist, endocrinologist, or lipid specialist
Coverage Duration	Initial 6 months. Renewal 12 months.

Other Criteria

For initial, Patient meets one of the following: A) Received at least 12 consecutive weeks of HIGH-INTENSITY statin and will continue to receive a high-intensity statin [ie, atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg] at maximally tolerated dose, B) Unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: Myalgia or Myositis AND Has been receiving at least 12 consecutive weeks of MODERATE- or LOW-INTENSITY statin and will continue to receive a moderate or low--intensity statin [i.e., atorvastatin 10-20 mg, Crestor (rosuvastatin) 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 20-80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 1-4 mg] at maximally tolerated doses, C) Labeled contraindication to all statins as documented in medical records or experienced rhabdomyolysis. For renewal, Patient continues to receive statin at the maximally tolerated dose (unless patient has documented inability to take statins) AND Submission of medical records (e.g., laboratory values) documenting a sustained reduction in LDL-C levels from pretreatment baseline (i.e., prior PCSK9 therapy) while on PCSK9 therapy AND Not used in combination with another PCSK9 inhibitor

PROCYSBI (S)

Products Affected

• Cystagon

• Procysbi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of nephropathic cystinosis AND Patient has tried and failed, or had an intolerance to, therapy with Cystagon (immediate-release cysteamine bitartrate)
Age Restrictions	6 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

PROLIA (BCBS RI)

Products Affected

• Prolia

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient is at high risk for fracture defined as one of the following: Personal history of low-trauma fractures as an adult, History of osteoporotic fracture in a first degree relative, Concurrent use of systemic corticosteroids (avg dose more than 5 mg of prednisone per day), Concurrent cigarette smoking, Low body weight less than 127 pounds, Low bone mineral density (T-score of -2.5 or lower) AND Diagnosis of one of the following: Patient is female and is receiving adjuvant aromatase inhibitor therapy for breast cancer, Patient is male and is receiving androgen deprivation therapy for non-metastatic prostate cancer, Patient is a male or postmenopausal female with a diagnosis of osteoporosis AND Patient has a documented trial and failure with a bisphosphonate (failure is defined as new fractures in compliant patients) or contraindication or intolerance to bisphosphonate therapy or is unable to comply with appropriate administration recommendations for oral or injectable bisphosphonate therapy AND Patient is concomitantly taking calcium 1000 mg daily and at least 400 IU vitamin D daily AND Patient will have pre-existing hypocalcemia and vitamin D deficiency corrected prior to administration of the medication
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Calcium, mineral, and vitamin D levels will be monitored periodically during treatment. Approvable under Part D only if patient is in a long term care facility OR the medication is not being administered with an infusion pump.

PROMACTA (S)

Products Affected

• Promacta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following: A) Relapsed/refractory chronic immune (idiopathic) thrombocytopenic purpura (ITP) for greater than 6 months AND Baseline platelet count is less than 50,000/mcL AND Degree of thrombocytopenia and clinical condition increase the risk of bleeding AND Patient had an insufficient response, intolerance, contraindication to corticosteroids or immune globulin or inadequate response or contraindication to splenectomy, B)Chronic hepatitis C and patient has thrombocytopenia defined as platelets less than 90,000/mcL for initiation (pre-treatment) of interferon therapy, or C) Severe aplastic anemia and patient has a platelet count less than 30,000/mcL and patient has an insufficient response, intolerance, or contraindication to immunosuppressive therapy with antithymocyte globulin and cyclosporine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ITP - 12 months. Hep C - 9 weeks (initial), 24 weeks (renewal)
Other Criteria	For renewal of ITP, after at least 4 weeks of therapy at the maximum weekly dose (10 mcg/kg) the platelet count increased to a sufficient level to avoid clinically important bleeding. For renewal of Hepatitis C, platelets less than 75,000/mcL for maintenance of optimal interferonbased therapy.

QUALAQUIN (S)

Products Affected

• Quinine Sulfate CAPS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Prolongation of QT interval. Glucose-6-phosphate dehydrogenase deficiency. Myasthenia gravis. Known hypersensitivity to mefloquine or quinidine. Optic neuritis.
Required Medical Information	Patient is being treated for uncomplicated Plasmodium falciparum malaria
Age Restrictions	16 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	One month
Other Criteria	Dosing will be approved per the FDA labeling.

RAVICTI (BCBS RI)

Products Affected

• Ravicti

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	acute hyperammonemia. N-acetylglutamate synthase (NAGS) deficiency
Required Medical Information	Diagnosis of urea cycle disorder involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamoylase (OTC), or argininosuccinic acid synthetase (AAS) confirmed via enzymatic, biochemical, or genetic testing AND protein-restricted diet alone or amino acid supplements alone has been ineffective AND patient has tried and had an inadequate response, is intolerant, or has a contraindication to Buphenyl for at least 3 months AND patient will maintain a protein-restricted diet while on therapy.
Age Restrictions	2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

RECLAST (S)

Products Affected

• Zoledronic Acid INJ 5MG/100ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded from Part D.
Exclusion Criteria	Creatinine clearance less than 35 mL/min or evidence of acute renal impairment. Hypocalcemia (corrected calcium level less than 8.0 mg/dL). Patient is currently receiving Zometa.
Required Medical Information	A) Postmenopausal female with osteoporosis diagnosed by BMD (T-score -2.5 or below) or history of fracture, B) Prevention of osteoporosis in postmenopausal female with one risk factor: Low BMD (T-score -1.5 or below), low BMI (less than 19 kg/m2), rheumatoid arthritis, Smoking, Alcohol use (more than 3 drinks/day), parental history of hip fracture, Equivalent dose of 5 mg prednisone or more/day for at least 3 months, C) Glucocorticoid-induced osteoporosis and one of following: postmenopausal female or male 50 years of age or older at high-risk for fracture (defined as History of osteoporotic fracture or Multiple risk factors for fracture such as: Low BMI (less than 19 kg/m2), female gender, rheumatoid arthritis, smoker, alcohol intake more than 3 drinks/day, parental history of hip fracture, or oral glucocorticoid therapy (5 mg or more prednisone daily or equivalent for at least 3 months) OR Postmenopausal female, male 50 years of age or older at medium or low risk for fracture, or younger patient with history of osteoporotic fracture and expected to be on 7.5 mg or higher daily dose of prednisone or equivalent for at least 3 months OR Premenopausal female or male 50 years of age or older without history of fracture AND expected to be on 7.5 mg of prednisone daily dose or equivalent for at least 12 months. G) Paget's disease of bone with one of the following: Serum alkaline phosphatase two times or more higher than the upper limit of the age-specific normal reference range, Symptomatic disease (i.e. bone pain, headache with skull involvement, back pain due to radiculopathy or arthropathy, fissure fractures), At risk for complications from the disease (e.g., those with active disease near neurovascular structures or major joints) AND For osteoporosis indications, inadequate response to oral bisphosphonates, unless contraindication/intolerance or is unable to comply with appropriate administration recommendations for oral bisphosphonate.
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For retreatment of Paget's disease, patient has relapsed, based on increases in serum alkaline phosphatase, or in those who failed to achieve normalization of their serum alkaline phosphatase, or in those patients with symptoms. For renewal of glucocorticoid-induced osteoporosis, patient is continuing to receive corticosteroids and is benefitting from therapy (e.g., improved or stabilized BMD, no new fractures, or improved biochemical markers). For renewal of other indications, patient is benefitting from therapy (e.g., improved or stabilized BMD, no new fractures, or improved biochemical markers).

RELISTOR (S)

Products Affected

• Relistor

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Known or suspected mechanical gastrointestinal obstruction. On renewal, patient does not have severe or persistent diarrhea.
Required Medical Information	Diagnosis of opioid-induced constipation AND Patient has used opioid medication for a minimum of 2 weeks AND Patient is experiencing fewer than 3 bowel movements in a week or no bowel movement for longer than 2 days AND Patient has tried and had an insufficient response to laxative (e.g., lubiprostone) therapy AND Patient is diagnosed one of the following: A) advanced illness (e.g., incurable cancer, end-stage chronic obstructive pulmonary disease/emphysema, cardiovascular disease/heart failure, Alzheimer's disease/dementia, HIV/AIDS, etc.) in a patient receiving palliative care or B) chronic non-cancer pain .
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	4 months
Other Criteria	For renewal, the patient has responded to therapy (i.e. increase in bowel movements)

REMICADE (R)

Products Affected

• Remicade

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis). Moderate to severe heart failure in patients receiving doses greater than 5 mg/kg.
Required Medical Information	Diagnosis of one of the following: A) moderate to severe rheumatoid arthritis and patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying antirheumatic drugs (DMARDs) and patient will be on concomitant methotrexate B) ankylosing spondylitis and patient had an inadequate response, intolerance or contraindication to one or more NSAIDs C) severe chronic plaque psoriasis (affecting more than 10% of body surface area or affecting crucial body areas such as the hands, feet, face, or genitals) and patient had an inadequate response, intolerance or contraindication to conventional therapy with at least one or more oral systemic treatments D) moderate to severe Crohn's disease and patient had an inadequate response, intolerance, or contraindication to conventional therapy with two or more of the following: corticosteroids or non-biologic DMARDs E) fistulizing Crohn's disease F) moderate to severe ulcerative colitis and patient had an inadequate response, intolerance or contraindication to conventional therapy with two or more of the following: corticosteroids, 5-ASA (i.e. mesalamine, sulfasalazine, balsalazide, olsalazine) or non-biologic DMARDs G) psoriatic arthritis and patient had an inadequate response, intolerance or contraindication to methotrexate.
Age Restrictions	6 years of age or older for UC or Crohn's disease (non-fistulizing). 18 years of age or older for all other indications, including fistulizing Crohn's disease
Prescriber Restrictions	N/A
Coverage Duration	Initial: 18 weeks (CD), 12 months (others). Renewal 12 months

Other Criteria

Patient has been tested for TB and latent TB has been ruled out or is being treated. For renewal, patient has stable disease or has improved while on therapy (For RA, improvement in tender/swollen joint count, improvement in ACR scoring. For PsA, improvement in number of swollen/tender joints, pain, stiffness. For AS, improvement in AS symptoms, such as stiffness and back pain. For CD, symptomatic remission. For UC, clinical remission, reduction in steroid use.)

REPATHA (S)

Products Affected

• Repatha

• Repatha Sureclick

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	HeFH/ASCVD (initial): Submission of medical records (eg, chart notes, laboratory values) documenting one of the following diagnoses: Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Documented assessment of patient using Dutch Lipid Clinic Network diagnostic criteria with a cumulative score greater than or equal to 9 points (ie, definite FH), or (2) Presence of tendinous xanthomas in patient, first degree relative, or second degree relative, AND Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, or (3) Genetic confirmation of a mutation in the LDL receptor, ApoB, or PCSK9. OR Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin. HoFH (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: (1) Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or (2) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL, AND either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents. HeFH/ASCVD/HoFH (initial): One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: (1) LDL-C greater than or equal to 100 mg/dL with ASCVD, or (2) LDL-C greater than or equal to 130 mg/dL without ASCVD.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a cardiologist, endocrinologist, or lipid specialist
Coverage Duration	Initial 6 months (HeFH, ASCVD), 12 weeks (HoFH). Renewal 12 months.

Other Criteria

HeFH/ASCVD (initial): One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one maximally-tolerated statin therapy and will continue to receive a statin at maximally tolerated dose, or (2) Patient is unable to tolerate statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), or (3) Patient has a labeled contraindication to all statins as documented in medical records, or (4) Patient has experienced rhabdomyolysis. History of failure after 12 consecutive weeks or intolerance to Praluent therapy. HoFH (initial): One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one maximally-tolerated statin therapy and will continue to receive a statin at maximally tolerated dose, or (2) both of the following: a) One of the following: 1. Patient is unable to tolerate statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), or 2. Patient has a labeled contraindication to all statins as documented in medical records, or 3. Patient has experienced rhabdomyolysis, AND b) patient has been receiving at least 12 consecutive weeks of other LDL-C lowering prescription therapies and will continue to receive an LDL-C lowering prescription therapy. HeFH/ASCVD (reauth): Patient continues to receive statin at the maximally tolerated dose (unless patient has documented inability to take statins). HoFH (reauth): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). HeFH/ASCVD/HoFH (reauth): Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pretreatment baseline (ie, prior to Repatha therapy) while on Repatha therapy. HeFH/ASCVD/HoFH (Initial, reauth): Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. HoFH (Initial, reauth): Not used in combination with Juxtapid (lomitapide) or Kynamro (mipomersen).

REVATIO (S)

Products Affected

• Revatio SUSR

• Sildenafil

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Receiving nitrate therapy (includes intermittent use)
Required Medical Information	Diagnosis of pulmonary arterial hypertension WHO Group I with New York Heart Association (NYHA) functional class II or III that was confirmed by right heart catheterization
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	6 months - initial. 12 months - renewal
Other Criteria	N/A

REVLIMID (S)

Products Affected

• Revlimid

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of multiple myeloma and medication will be used in combination with dexamethasone OR diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities OR Diagnosis of mantle cell lymphoma and patient's disease has relapsed or progressed after trying at least two prior therapies including Velcade AND patient is enrolled in the Revlimid REMS Program AND patient is not using the medication for the treatment of chronic lymphocytic leukemia
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

RITUXAN (BCBS RI)

Products Affected

• Rituxan INJ 500MG/50ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Severe, active infection.
Required Medical Information	Diagnosis of one of the following: A) non-Hodgkin's lymphoma B) chronic lymphocytic leukemia C) granulomatosis with polyangiitis (GPA, Wegener's granulomatosis) and is receiving concurrent glucocorticoid therapy D) microscopic polyangiitis and is receiving concurrent glucocorticoid therapy E) moderate to severe rheumatoid arthritis and patient had an inadequate response, intolerance or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs for at least 3 consecutive months and patient has tried and had an inadequate response, intolerance or contraindication to both Humira and Enbrel.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has been screened for hepatitis B virus infection and does not have HBV reactivation. For renewal of RA, patient has stable disease or has improved while on therapy (e.g., improvement in tender/swollen joint count, improvement in ACR scoring) and it has been 16 weeks since the last course of treatment.

SABRIL (S)

Products Affected

• Sabril

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following: A) infantile spasms B) complex partial seizures and patient had an inadequate response to at least one generic first-line agents (carbamazepine, lamotrigine, levetiracetam, oxcarbazepine, valproic acid, divalproex sodium) and at least one adjunctive agent (carbamazepine, clobazam, gabapentin, lamotrigine, levitiracetam, oxcarbazepine, valproic acid, divalproex sodium, topiramate) AND patient and prescriber are enrolled in the SHARE restricted distribution program.
Age Restrictions	seizures - 10 years of age or older. Infantile spasms - at least one month to 2 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

SANDOSTATIN (S)

Products Affected

• Octreotide Acetate

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of acromegaly and patient had an inadequate response or cannot be treated with surgical resection, pituitary irradiation, and/or bromocriptine mesylate at maximally tolerated doses OR Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea and flushing episodes OR Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal of acromegaly, IGF-1 level has normalized or improved. For renewal of metastatic carcinoid tumor, patient has improvement in diarrhea and flushing episodes. For renewal of vasoactive intestinal peptide tumor, improvement in diarrhea episodes.

SANDOSTATIN LAR (S)

Products Affected

• Sandostatin Lar Depot

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of acromegaly and patient had an inadequate response or cannot be treated with surgical resection, pituitary irradiation, and/or bromocriptine mesylate at maximally tolerated doses OR Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea and flushing episodes OR Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea AND Patient received at least two weeks of Sandostatin Injection and has tolerated therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal of acromegaly, IGF-1 level has normalized or improved. For renewal of metastatic carcinoid tumor, patient has improvement in diarrhea and flushing episodes. For renewal of vasoactive intestinal peptide tumor, improvement in diarrhea episodes.

SAVELLA (S)

Products Affected

• Savella

• Savella Titration Pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Use of monoamine oxidase inhibitors concomitantly or within 14 days.
Required Medical Information	Diagnosis of fibromyalgia AND patient had a previous trial with or has a contraindication, intolerance, or allergy to one of the following agents used for the treatment of fibromyalgia: tricyclic antidepressant, SNRI, SSRI, gabapentin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal patient had an improvement in pain, physical functioning, etc.

SEROSTIM (S)

Products Affected

• Serostim

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure. Active malignancy. Active proliferative or severe non-proliferative diabetic retinopathy.
Required Medical Information	Diagnosis of AIDS-wasting syndrome or cachexia (defined as unintentional weight loss of at least 10% of baseline weight) AND Treatment failure with or intolerance to dronabinol AND Patient is currently receiving treatment with antiretrovirals
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 weeks
Other Criteria	For renewal, patient has experienced an increase in body weight and/or improvement in lead body mass AND wasting is still evident

SIGNIFOR (S)

Products Affected

• Signifor

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of (pituitary) Cushing's disease AND pituitary surgery is not an option or has not been curative
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient had a clinically meaningful reduction in 24-hour urinary free cortisol levels and/or improvement in signs or symptoms of the disease

SIGNIFOR LAR (S)

Products Affected

• Signifor Lar

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of acromegaly and patient had an inadequate response to surgery or patient is not a candidate for surgery
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months initial. 12 months renewal
Other Criteria	For renewal, patient's growth hormone level or insulin-like growth factor 1 (IGF-1) level for age and gender has normalized/improved.

SIMPONI (BCBS RI)

Products Affected

• Simponi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis)
Required Medical Information	Diagnosis of one of the following: A) moderate to severe rheumatoid arthritis and patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying antirheumatic drugs (DMARDs) for at least 3 consecutive months and patient will be on concomitant methotrexate B) psoriatic arthritis and patient had an inadequate response, intolerance, or contraindication to methotrexate C) ankylosing spondylitis and patient had an inadequate response, intolerance or contraindication to one or more NSAIDs D) moderately to severely active ulcerative colitis and patient has had inadequate responses to, is intolerant to, or is contraindicated to conventional therapy with two or more of the following: Corticosteroids (i.e. prednisone, methylprednisolone), 5-ASAs (i.e. mesalamine, sulfasalazine, balsalazide, olsalazine), or Non-biologic DMARDs (i.e. azathioprine, methotrexate, mercaptopurine)
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Initial 10 weeks (UC), 12 months others. Renewal 12 months.
Other Criteria	Patient has been tested for TB and latent TB has been ruled out or is being treated. For renewal, patient has stable disease or has improved while on therapy (e.g., for RA, improvement in tender/swollen joint count, improvement in ACR scoring. For PsA, improvement in number of swollen/tender joints, pain, stiffness. For AS, improvement in AS symptoms, such as stiffness and back pain. For UC, clinical remission, reduction in steroid use.)

SIMPONI ARIA (BCBS RI)

Products Affected

• Simponi Aria

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis)
Required Medical Information	Diagnosis of moderate to severe rheumatoid arthritis and patient had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs)for at least 3 consecutive months and patient will be on concomitant methotrexate
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months.
Other Criteria	Patient has been tested for TB and latent TB has been ruled out or is being treated. For renewal, patient has stable disease or has improved while on therapy (e.g., for RA, improvement in tender/swollen joint count, improvement in ACR scoring.)

SIMVASTATIN (S)

Products Affected

• Simvastatin TABS 80MG

• Vytorin TABS 10MG; 80MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active liver disease. Pregnancy. Nursing. Patient is taking or initiating therapy with any of the following: verapamil, diltiazem, amiodarone, dronedarone, amlodipine, ranolazine, strong CYP3A4 inhibitors (i.e., itraconazole, ketoconazole, posaconazole, protease inhibitors, erythromycin, clarithromycin, telithromycin, and nefazodone), gemfibrozil, cyclosporine, and danazol.
Required Medical Information	Patient has been taking simvastatin 80 mg chronically (12 months or more) without evidence of muscle toxicity AND, if patient is of Chinese descent, they are not concurrently receiving lipid-modifying doses (at least 1 gram/day) of niacin-containing products
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

SOMATULINE DEPOT (S)

Products Affected

• Somatuline Depot

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of: A) acromegaly AND Inadequate response to surgery and/or radiation therapy or patient is not a candidate for surgery and/or radiotherapy, B) unresectable, well-or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient's IGF-1 levels for age and gender has normalized or improved.

SOMAVERT (S)

Products Affected

• Somavert

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of acromegaly AND Inadequate response to surgery and/or radiation therapy and/or other medical therapies (such as dopamine agonists) AND patient had an inadequate response or intolerance to generic octreotide OR patient is not a candidate for any of those treatment options.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, Patient has experienced a decrease or normalization of insulin-like growth factor-1 (IGF-1) levels.

SOVALDI (R)

Products Affected

• Sovaldi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of CHC AND for G1 only inadequate response, contraindication, or intolerance to Harvoni AND A) used with RBV and PEG-IFN and one of the following: i) G3-6 and tx naive, ii) G2-4 and tx failure with PEG-IFN and RBV, iii) G2-3 and tx failure with SOF and RBV, iv) tx experienced G5-6, or v) G1, OR B) Used with RBV and one of the following: i) tx naïve in G2-4, ii) G2 or 4 and tx failure with PEG-IFN + RBV, iii) G2-3 in transplant pt with or without cirrhosis, or C) Used with Daklinza and RBV in one of the following: i) G1-4 with decompensated cirrhosis or transplant recipient, ii) G3, IFN-ineligible and tx failure with PEG-IFN and RBV or SOF and RBV D) Used with Daklinza and one of the following: i) tx naive G1 or 3 ii) tx naive G2, RBV-intolerant iii) G1 failed therapy with PEG-IFN and RBV with or without HCV protease inhibitor without cirrhosis or with compensated cirrhosis iv) G3 without cirrhosis, failed tx with PEG-IFN and RBV, or v) G2 IFN-ineligible patient who failed therapy with SOF and RBV vi) G1 or 4 decompensated cirrhosis and RBV intolerant, vii) G1-4 in patients who received a liver transplant and RBV intolerant E) Used with Olysio and G1 and one of the following: i) tx naive without cirrhosis, ii) tx naive with compensated cirrhosis if G1a without Q80K polymorphism or G1b iii) tx failure on PEG-IFN and RBV with compensated cirrhosis, iv) tx experienced with PEG-IFN and RBV with compensated cirrhosis if G1a without Q80K polymorphism or G1b, v) post-transplant F) Hepatocellular carcinoma and meets Milan criteria for liver transplant (i.e. a single HCC nodule with a maximum size of 5 cm or as many as 3 nodules with the largest not exceeding 3 cm and no macrovascular invasion). Authorization for 24 weeks when in cirrhosis, IFN-ineligible, used with Daklinza in transplant patient and RBV intolerant, or used with RBV in G4 or G2 who failed RBV and PEG-IFN. Authorization for 48 weeks in hepatocellular carcinoma OR G2 or 3 and decompensated cirrhosis.
Age Restrictions	N/A
Prescriber Restrictions	hepatologist, gastroenterologist, or infectious disease specialist

Coverage Duration	12 wks. 24 wks or 48 weeks as outlined in required medical information section
Other Criteria	N/A

SPORANOX (S)

Products Affected

• Sporanox SOLN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Ventricular dysfunction. Congestive heart failure (CHF). History of CHF. Concurrent therapy with certain drugs metabolized by CYP3A4 (e.g., cisapride, lovastatin, methadone, etc.)
Required Medical Information	Patient meets one of the following conditions: A) Diagnosis of systemic fungal infection (e.g., aspergillosis, histoplasmosois, blastomycosis) OR B) Diagnosis of onychomycosis confirmed by one of the following: positive potassium hydroxide (KOH) preparation, culture, or histology and the patient has extensive nail involvement causing significant pain and/or debilitation and Patient has tried and failed oral terbinafine OR C) Diagnosis of one of the following: tinea corporis (ringworm), tinea cruris (jock itch), tinea pedis (athlete's foot), tinea capitis (scalp ringworm), pityriasis versicolor and the patient is resistant to topical treatment OR the patient has a diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to fluconazole (oral solution only) AND patient is not pregnant
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Systemic: 6 mos. Non-Systemic: 3 mos.
Other Criteria	N/A

SPRYCEL (BCBS RI)

Products Affected

• Sprycel

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. GIST.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in the chronic phase and patient is found to be Ph+ or BCR-ABL positive as detected by bone marrow cytogenetics or FISH OR Ph+ CML with resistance, relapse or inadequate response to prior TKI therapy (e.g., Gleevec, Tasigna, Iclusig, Bosulif) and if patient has mutation testing, patient does not have T315I mutation OR Ph+ CML with intolerance to prior therapy OR Diagnosis of Ph+ acute lymphoblastic leukemia OR Gastrointestinal stromal tumors (GIST) after disease progression on Gleevec (imatinib) or Sutent (sunitinib)
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

STELARA (BCBS RI)

Products Affected

• Stelara

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis [TB]) BCG during and 1 year prior to treatment
Required Medical Information	Diagnosis of one of the following: A) moderate to severe plaque psoriasis (affecting more than 5% of the body surface area or affecting crucial body areas such as the hands, feet, face, or genitals) AND patient tried and had an inadequate response, is intolerant of, or is contraindicated to conventional therapy with at least one of the following: phototherapy (including but not limited to, psoralen with ultraviolet-a [PUVA] and/or retinoids [rePUVA]) for at least one continuous month or oral systemic treatment (e.g., methotrexate, cyclosporine, acitretin) for at least 3 consecutive months B) psoriatic arthritis and patient had an inadequate response, intolerance, or contraindication to methotrexate.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has been tested for latent TB infection and latent TB has been ruled out or is being treated per guidelines. Dosing as per FDA approved labeling. For renewal, patient has stable disease or has improved while on therapy (e.g., for PsA, improvement in number of swollen/tender joints, pain, stiffness). Starting dose is 45mg. 90mg only if the patient has tried and failed 45mg AND is over 100kg.

STIVARGA (S)

Products Affected

• Stivarga

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of: A) metastatic colon or rectal cancer AND patient has previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based therapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if KRAS wild type, an anti-epidermal growth factor receptor (EGFR) therapy or B) gastrointestinal stromal tumors that is locally advanced, unresectable or metastatic and patient has tried and had an inadequate response, contraindication or intolerance to Gleevec or Sutent.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	If patient has elevated liver function tests of hepatocellular necrosis, therapy will be interrupted and then reduced or discontinued.

STRENSIQ (S)

Products Affected

• Strensiq INJ 40MG/ML, 80MG/0.8ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia (HPP).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism.
Coverage Duration	12 months
Other Criteria	80mg/0.8 mL strength: Patient's weight is greater than or equal to 40 kg

SUBUTEX (S)

Products Affected

• Buprenorphine Hcl SUBLINGUAL SUBL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of opioid dependence AND Prescription is a part of an overall treatment program (e.g., self-help groups, counseling, provide ongoing care, vocational training) AND Patient is not receiving any other opioids since starting therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is certified through SAMHSA (Substance Abuse and Mental Health Services Administration) to prescribe Suboxone and provide registration number
Coverage Duration	Initial - 3 months (pregnant) or 1 month (not pregnant). Renewal - 9 months
Other Criteria	For renewal, patient meets all initial criteria and prescriber is evaluating random urine drug screens and assessing the patient's progress (e.g., relapse, progress/accomplishment of treatment goals)

SUTENT (S)

Products Affected

• Sutent

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of advanced/metastatic renal cell carcinoma OR Diagnosis of gastrointestinal stromal tumors after disease progression on or intolerance to Gleevec OR Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

SYLATRON (S)

Products Affected

• Sylatron

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	autoimmune hepatitis. Hepatic decompensation (Child-Pugh score greater than 6 [Class B or C])
Required Medical Information	Patient is being treated adjuvantly for melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

SYLVANT (S)

Products Affected

• Sylvant INJ 100MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of multicentric Castleman's disease AND patient is HIV negative AND patient is human herpes virus-8 (HHV-8) negative
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient has not experienced treatment failure defined as disease progression based on increase in symptoms, radiologic progression, or deterioration in performance status

SYMLIN (S)

Products Affected

• Symlinpen 120

• Symlinpen 60

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Confirmed diagnosis of gastroparesis. Concurrent use of drugs that stimulate gastrointestinal motility. Recurrent severe hypoglycemia requiring assistance during the past 6 months. Presence of hypoglycemia unawareness. Poor compliance with current insulin regimen. Poor compliance with prescribed self-blood glucose monitoring. Hemoglobin A1c level higher than 9%.
Required Medical Information	Diagnosis of type 1 or type 2 diabetes mellitus AND Patient has failed to achieve desired glucose control despite optimal insulin therapy AND Patient is taking concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog) AND patient is receiving ongoing care and guidance for their diabetes
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient has an improvement in hemoglobin A1c from baseline.

SYNAGIS (S)

Products Affected

• Synagis

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient will use palivizumab for immunoprophylaxis of respiratory syncytial virus (RSV) during the peak months of infection in the patient's geographic region AND Patient meets one of the following criteria: A) Infants born at 28 weeks, six days gestation or earlier and who are younger than 12 months of age at the start of the RSV season OR B) Infants born at 29 to 31 weeks, six days gestation and who are younger than six months of age at the start of the RSV season OR C) Infants born at 32 to 34 weeks, six days gestation and who are younger than three months of age at the start of RSV season with at least one of the following risk factors may be dosed until 90 days of age: Child care attendance or Sibling younger than five years of age living in the same household (who is not a multiple birth younger than one year of age) OR D) Infants and children younger than one year of age at the start of RSV season with either congenital abnormalities of the airway or neuromuscular disease that compromises handling of respiratory secretions OR E) Infants and children younger than two years of age with hemodynamically significant congenital heart disease and who have at least one of the following criteria: Receiving medication to control congestive heart failure, Has moderate to severe pulmonary hypertension, or Has cyanotic heart disease OR F) Infants and children younger than two years of age who have received medical therapy (oxygen, bronchodilator, diuretic, or corticosteroid therapy) for chronic lung disease within six months of the start of the RSV season
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve 5 doses based on patient body weight.

SYNRIBO (S)

Products Affected

• Synribo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of chronic myelogenous leukemia AND patient has tried and failed or has a contraindication or intolerance to 2 tyrosine kinase inhibitors
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

TACLONEX (S)

Products Affected

• Taclonex SUSP

• Calcipotriene/betamethasone Dipropionate

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of stable psoriasis vulgaris (plaque psoriasis) AND Patient tried adequate therapy with at least one of the following agents: medium to high potency topical steroid (unless contraindicated/intolerant without concurrent vitamin D analog use) or vitamin D analogs (unless contraindicated/intolerant without concurrent steroid use) or tazarotene (unless contraindicated/intolerant to its use)\
Age Restrictions	Scalp: 12 or older. Body: 18 and older.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, has the patient's symptoms have improved

TAFINLAR (S)

Products Affected

• Tafinlar

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of unresectable or metastatic melanoma and medication will be used as a single agent in a patient with a positive BRAF V600E mutation as detected by an FDA-approved test (THxID-BRAF Kit) or Clinical Laboratory Improvement Amendments (CLIA)-approved facility OR medication will be used in combination with Mekinist in a patient with BRAF V600E or V600K mutation, as detected by an FDA-approved test (THxID-BRAF kit) or Clinical Laboratory Improvement Amendments (CLIA)-approved facility.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

TAGRISSO (S)

Products Affected

• Tagrisso

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Tumors are positive for epidermal growth factor receptor (EGFR) T790M mutation.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy. NSCLC: The patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib).

TARCEVA (S)

Products Affected

• Tarceva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer and Tarceva will be used in combination with gemcitabine OR Diagnosis of locally advanced or metastatic (stage III or IV) non-small cell lung cancer with one of the following: A) failure with at least one prior chemotherapy regimen and Tarceva will be used as monotherapy, or B) no evidence of disease progression after four cycles of first-line platinum-based chemotherapy and Tarceva will be used as maintenance treatment and Tarceva will be used as monotherapy, or C) Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

TARGRETIN (S)

Products Affected

• Bexarotene

• Targretin

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of cutaneous T-cell lymphoma (CTCL) and patient is not a candidate for or had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) for cutaneous manifestations of CTCL
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Female patients of child-bearing potential have a documented negative pregnancy test one week prior to the initiation of therapy. For renewal, Patient has not had disease progression while on therapy and female patients of child-bearing potential are not pregnant and are continuing to use adequate birth-control measures during therapy.

TASIGNA (BCBS RI)

Products Affected

• Tasigna

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. GIST.
Exclusion Criteria	Long QT syndrome. Uncorrected hypokalemia. Uncorrected hypomagnesemia. Concomitant use with a drug known to prolong the QT interval or strong cytochrome P450 3A4 inhibitors
Required Medical Information	Diagnosis of one of the following: A) newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in the chronic phase and patient is found to be Ph+ or BCR-ABL positive as detected by bone marrow cytogenetics or FISH OR Diagnosis of Ph+ CML with resistance, relapse or inadequate response to prior therapy and if the patient had mutation testing, patient does not have the T315I mutation OR Ph+ CML with intolerance to prior therapy B) Gastrointestinal stromal tumors after disease progression on Gleevec or Sutent
Age Restrictions	18 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

TAZORAC (BCBS RI)

Products Affected

• Tazorac

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy.
Required Medical Information	Diagnosis of acne vulgaris and patient has tried an adequate trial (at least two weeks) with at least one other topical acne product (e.g., benzoyl peroxide, salicylic acid, clindamycin, erythromycin, adapalene, azelaic acid, and/or tretinoin) OR Diagnosis of stable moderate to severe plaque psoriasis and 20% or less body surface area involvement and patient has a contraindication or tried adequate trial (at least 2 weeks) with at least one other topical psoriasis product (e.g., medium to high potency corticosteroid and/or vitamin D analogs) AND females of child-bearing potential are using adequate birth control measures during therapy.
Age Restrictions	12 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

TECENTRIQ (S)

Products Affected

• Tecentriq

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of locally advanced or metastatic urothelial carcinoma. One of the following: A) History of disease progression during or following platinum-containing chemotherapy, OR B) History of disease progression within 12 months of neoadjuvant or adjuvant treatment with a platinum-containing chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

TECFIDERA (S)

Products Affected

• Tecfidera

• Tecfidera Starter Pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting MS or progressive-relapsing MS, or secondary-progressive MS) OR patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, Patient had an objective response to therapy (ie no or slowed progression of disease)

TECHNIVIE (S)

Products Affected

• Technivie

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Severe hepatic impairment. Concomitant use with drugs highly dependent on cytochrome P450 enzyme (CYP) 3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events. Concomitant use with drugs that are moderate or strong inducers of CYP3A. Known hypersensitivity to ritonavir (e.g., toxic epidermal necrolysis or Stevens-Johnson syndrome). Concomitant use with any of the following: Alpha-1 adrenoreceptor antagonist: alfuzosin, Anticonvulsants: carbamazepine, phenytoin, phenobarbital, Antimycobacterial: rifampin, Ergot derivatives: ergotamine, dihydroergotamine, ergonovine, methylergonovine, Ethinyl estradiol-containing products: oral contraceptives, Herbal products: St. John's Wort, HMG-CoA reductase inhibitors: lovastatin, simvastatin, Neuroleptics: pimozide, Non-nucleoside reverse transcriptase inhibitor: Efavirenz, Phosphodiesterase-5 inhibitor: sildenafil when dosed as REVATIO, Sedative hypnotics: triazolam, orally-administered midazolam.
Required Medical Information	Patient has a diagnosis of chronic hepatitis C virus (HCV) genotype 4 infection AND Patient does not have cirrhosis AND TECHNIVIE will be used in combination with ribavirin (unless patient is treatment-naïve and cannot tolerate, or has a contraindication to, ribavirin) AND Patient will not use another HCV protease inhibitor (e.g., OLYSIO) or nucleotide analog polymerase inhibitor (i.e. SOVALDI, HARVONI) in combination with TECHNIVIE
Age Restrictions	N/A
Prescriber Restrictions	hepatologist, gastroenterologist, or infectious disease specialist
Coverage Duration	12 weeks.
Other Criteria	N/A

THALOMID (S)

Products Affected

• Thalomid

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of multiple myeloma that is newly diagnosed and is receiving concurrent dexamethasone OR Diagnosis of severe erythema nodosum leprosum with cutaneous manifestations and the medication will not be used as monotherapy if the member has moderate to severe neuritis
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is registered and the member is enrolled in the Thalomid REMS program
Coverage Duration	12 months
Other Criteria	N/A

TOPICAL RETINOIDS (S)

Products Affected

- Avita
- Tretinoin EXTERNAL CREA
- Tretinoin EXTERNAL GEL
- Tretinoin Microsphere

- Tretinoin Microsphere Pump
- Tretin-x
- Veltin
- Ziana

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of mild to moderate acne vulgaris (including comedonal, cystic, and nodular)
Age Restrictions	PA applies to patients older than 26 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, medication has been effective in treating the patient's condition.

TRACLEER (S)

Products Affected

• Tracleer

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Receiving concomitant cyclosporine A or glyburide therapy.
Required Medical Information	Diagnosis of pulmonary arterial hypertension WHO Group I with New York Heart Association (NYHA) functional class II-IV that was confirmed by right heart catheterization AND patient has been enrolled into the TAP Restricted Distribution Program
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months - initial. 12 months - renewal
Other Criteria	N/A

TRELSTAR (S)

Products Affected

• Trelstar Mixject

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of advanced or metastatic prostate cancer
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

TYKERB (S)

Products Affected

• Tykerb

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND a) the medication will be used in combination with Xeloda in a patient with advanced or metastatic disease and the patient has received prior therapy including an anthracycline, a taxane, and trastuzumab or b) The medication will be used in combination with Femara for the treatment of a postmenopausal woman with hormone receptor-positive metastatic disease for whom hormonal therapy is indicated.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient's hepatic function has been assessed prior to starting therapy.

Tysabri (r)

Products Affected

• Tysabri

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	History of progressive multifocal leukoencephalopathy.
Required Medical Information	Diagnosis of relapsing form of multiple sclerosis and medication will be used as monotherapy and patient had an inadequate response, intolerance, or contraindication to one of the following: An interferon beta product, Copaxone, Gilenya, Aubagio, or Tecfidera OR Diagnosis of moderate to severe active Crohn's disease and medication will not be used in combination with immunosuppressants or inhibitors of tumor necrosis factor-alfa and patient had an inadequate response, intolerance, or contraindication to HUMIRA.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient and physician are registered in the TOUCH prescribing program.

TYZEKA (S)

Products Affected

• Tyzeka

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Co-administration with pegylated interferon alfa-2a
Required Medical Information	Diagnosis of chronic hepatitis B AND patient is HBsAg-positive for at least 6 months AND For HBeAg-positive patients, serum HBV DNA greater than 20,000 IU/mL (105 copies per mL) and for HBeAg-negative patients, serum HBV DNA greater than 2,000 IU/mL (104 copies/mL) AND Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) at least 2 times the upper limit of normal or histologically active disease (i.e. necroinflammation on biopsy)
Age Restrictions	16 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient must be HBeAg negative and have not had HBsAg clearance OR HBeAg positive and have detectable HBV DNA and have not been anti-Hbe for at least 6 months

UPTRAVI (S)

Products Affected

• Uptravi

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of pulmonary arterial hypertension (PAH) AND Patient is symptomatic AND One of the following: a) Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization OR b) patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension. Reauth: Documentation of positive clinical response to Uptravi therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist
Coverage Duration	Initial: 6 months Reauth: 12 months
Other Criteria	Initial: One of the following: a) History of inadequate response, contraindication, or intolerance to a PDE5 inhibitor (ie, Adcirca, Revatio) or Adempas (riociguat), and History of inadequate response, contraindication, or intolerance to an endothelin receptor antagonist [e.g. Letairis (ambrisentan), Opsumit (macitentan), or Tracleer (bosentan)] OR b) For continuation of prior Uptravi therapy. Initial/Reauth:Not taken in combination with a prostanoid/prostacyclin analogue (eg, epoprostenol, iloprost, treprostinil)

VALCHLOR (BCBS RI)

Products Affected

• Valchlor

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of mycosis fungoides-type cutaneous T-cell lymphoma AND patient has early stage disease (defined as Stage 1A or 1B) AND patient has received prior skin-directed therapy (e.g., very high potency class I topical corticosteroids for at least 3 months (i.e. clobetasol, diflorasone, halobetasol, augmented betamethasone diproprionate), phototherapy, topical nitrogen mustard, or a topical retinoid (e.g., bexarotene)).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

VARIZIG (S)

Products Affected

• Varizig INJ 125UNIT/1.2ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	History of hypersensitivity (including anaphylaxis or severe systemic reaction) to immune globulin or any component of the preparation. Severe thrombocytopenia or coagulation disorder where IM injections are contraindicated.
Required Medical Information	Medication will be given through the intramuscular route AND The medication will be used for passive immunization for one of varicella.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A

VECTIBIX (S)

Products Affected

• Vectibix INJ 100MG/5ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of wild-type KRAS metastatic colorectal carcinoma
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	BvD determination

VENCLEXTA (S)

Products Affected

• Venclexta

• Venclexta Starting Pack

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL with 17p deletion or TP53 mutation. Patient has received at least one prior therapy for CLL/SLL [e.g., Cytoxan (cyclophosphamide), Fludara (fludarabine), Rituxan (rituximab)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

VIBERZI (S)

Products Affected

• Viberzi

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) AND history of failure, contraindication, or intolerance to antidiarrheal agents (e.g., loperamide)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial 12 weeks. Renewal 12 months
Other Criteria	For renewal, Patient experienced a positive clinical response to VIBERZI therapy as demonstrated by at least one of the following: improvement in abdominal cramping/pain or improvement in stool frequency and consistency.

VICTRELIS(BCBS RI)

Products Affected

• Victrelis

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnant. Unwilling to comply with required contraception methods. Coadministration with alfuzosin, carbamazepine, cisapride, dihydroergotamine, drosperinone, ergonovine, ergotamine, lovastatin, methylergonovine, midazolam (oral), phenobarbital, phenytoin, pimozide, rifampin, sildenafil (Revatio), simvastatin, St. John's wort, tadalafil (Adcirca), triazolam.
Required Medical Information	Diagnosis of chronic hepatitis C genotype 1 with compensated liver disease AND medication will be used with ribavirin and peginterferon alfa AND Has not previously failed a treatment regimen with a hepatitis C protease inhibitor.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Written by or in consultation with a gastroenterologist, hepatologist or ID specialist
Coverage Duration	Initial - 12 weeks. Renewal - duration based on FDA approved labeling
Other Criteria	For renewal, approval is based on the requirements outlined in the FDA-approved labeling, including viral load, presence of cirrhosis, and response to prior therapy and confirm that the patient is continuing to receive concurrent therapy with ribavirin and peginterferon alfa.

VIDAZA (S)

Products Affected

• Azacitidine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Advanced malignant hepatic tumor.
Required Medical Information	Patient has a diagnosis of myelodysplastic syndrome
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

VIEKIRA (R)

Products Affected

• Viekira Pak

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Severe hepatic impairment (Child-Pugh C). Known hypersensitivity to ritonavir (e.g., toxic epidermal necrolysis or Stevens-Johnson syndrome). Concomitant use with drugs that are highly dependent on cytochrome P450 enzyme (CYP)3A for clearance, strong inducers of CYP3A and CYP2C8, and strong inhibitors of CYP2C8. Concomitant use with any of the following medications: Alfuzosin, Carbamazepine, phenytoin, phenobarbital, Gemfibrozil, Rifampin, Ergotamine, dihydroergotamine, ergonovine, methylergonovine, Ethinyl estradiol-containing medications, such as combined oral contraceptives, St. John's Wort, Lovastatin, simvastatin, Pimozide, Sildenafil (REVATIO), Triazolam, orally-administered midazolam. Decompensated cirrhosis. Patient will not use another HCV protease inhibitor (e.g., OLYSIO) or nucleotide analog polymerase inhibitor (i.e. SOVALDI, HARVONI) in combination with VIEKIRA.
Required Medical Information	Patient has a diagnosis of chronic hepatitis C virus (HCV) genotype 1 infection AND Patient has tried and had an inadequate response, contraindication, or intolerance to HARVONI AND The patient meets one of the following: a) Genotype 1a with compensated cirrhosis AND VIEKIRA will be used with ribavirin, b) Genotype 1a without cirrhosis AND VIEKIRA will be used with ribavirin, c) Liver transplant recipients without cirrhosis and Metavir fibrosis score 2 or less AND VIEKIRA will be used with ribavirin, d) Genotype 1b infection without cirrhosis AND VIEKIRA will be used alone, or e) Genotype 1b infection with compensated cirrhosis.
Age Restrictions	N/A
Prescriber Restrictions	hepatologist, gastroenterologist, or infectious disease specialist
Coverage Duration	12 weeks: G1a no cirrhosis, G1b. 24 weeks: G1a cirrhosis, liver transplant
Other Criteria	N/A

VOTRIENT (S)

Products Affected

Votrient

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of advanced/metastatic renal cell carcinoma OR Diagnosis of advanced soft tissue sarcoma and patient received at least one prior chemotherapy (e.g., ifosfamide, doxorubicin, cisplatin, dacarbazine, docetaxel, oxaliplatin, etc.)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

VPRIV (S)

Products Affected

• Vpriv

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of type 1 Gaucher disease
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

XALKORI (S)

Products Affected

• Xalkori

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of locally advanced or metastatic (stage III or IV) non-small cell lung cancer AND Patient has alkaline phosphatase (ALK)-positive disease as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

XELJANZ (BCBS RI)

Products Affected

• Xeljanz

• Xeljanz Xr

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active serious infection (including tuberculosis). Combined use with a biologic disease-modifying anti-rheumatic drugs or potent immunosuppressant (e.g., azathioprine or cyclosporine)
Required Medical Information	Diagnosis of moderately to severely active rheumatoid arthritis AND patient tried and had an inadequate response, intolerance or contraindication to methotrexate or other non-biologic disease modifying anti-rheumatic drugs for at least 3 consecutive months AND patient has tried and failed at least 2 of the following: Enbel, Humira, Actemra, Cimzia, Orencia, Remicade, Simponi, unless there is a clinical reason to not use an injected product (e.g., fear of needles), patient has been tested for tuberculosis (TB) infection in the past year and latent TB has been ruled out or is being treated per guidelines.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient has stable disease or has improved while on therapy (e.g., improvement in tender/swollen joint count, improvement in ACR scoring)

XENAZINE (S)

Products Affected

• Tetrabenazine

• Xenazine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Tourette's syndrome.
Exclusion Criteria	Actively suicidal. Untreated or inadequately treated depression. Impaired hepatic function. Concomitant use of monoamine oxidase inhibitors or within a minimum of 14 days after discontinuing a MAOI. Concomitant use of reserpine or within 20 days of discontinuing reserpine.
Required Medical Information	Diagnosis of chorea associated with Huntington's disease or tardive dyskinesia with failure of at least one previous therapy (e.g., amantadine, benzodiazepines, haloperidol, atypical antipsychotics, etc.) or Gilles de la Tourette's syndrome with failure or least one previous therapy (e.g., antipsychotic agents, clonidine) AND any medication possibly contributing to the underlying symptoms of chorea and/or tardive dyskinesia has been discontinued (e.g., anticonvulsants, antipsychotics, metoclopramide, amphetamines, etc.) unless cessation would be detrimental to the underlying condition AND patients who require doses greater than 50 mg/day will be genotyped for CYP2D6 to determine whether the patient is a poor, intermediate or extensive metabolizer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, patient had lack of progression of disease or improvement in abnormal movements.

XEOMIN (S)

Products Affected

• Xeomin INJ 200UNIT, 50UNIT

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Hypersensitivity to human albumin or sucrose. Presence of infection at the proposed injection site(s).
Required Medical Information	Diagnosis of blepharospasm and patient has been previously treated with Botox OR cervical dystonia (spasmodic torticollis) AND Xeomin will not be used for cosmetic uses (e.g., wrinkles)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal of cervical dystonia, patient experienced improvement in at least one of the following: pain, severity of abnormal head position, or effects on the patient's daily activities. For renewal of blepharospasm, patient experienced an improvement in symptoms (e.g., ability to open eyes, improvement in blinking/spasms of the eye).

XGEVA (S)

Products Affected

• Xgeva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Hypocalcemia (calcium less than 8.0 mg/dL).
Required Medical Information	Diagnosis of one of the following: A) a solid tumor (e.g., breast cancer, castrate-resistant prostate cancer, thyroid carcinoma, kidney, or non-small cell lung cancer) and patient has bone metastases and Medication will be used for the prevention of skeletal-related events (e.g., fracture, spinal cord compression, hypercalcemia, bone pain or lesions requiring radiation or surgery) and patient has tried and had an inadequate response, contraindication, or intolerance to at least one generic intravenous bisphosphonate B) giant cell tumor of bone and Tumor is unresectable or surgical resection is likely to result in severe morbidity and patient is an adult or skeletally-mature adolescent, C) hypercalcemia of malignancy AND the patient has had a trial and inadequate response or intolerance to intravenous bisphosphonate treatment (unless the patient has renal failure) AND Patient has a corrected serum calcium level greater than 12.5 mg/dL
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Renewal of giant cell tumor of bone, tumor size is reduced. For renewal of bone metastases from solid tumors, skeletal-related events such as fractures have decreased or stabilized.

XIFAXAN (S)

Products Affected

• Xifaxan

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Allergy to rifamycin agents
Required Medical Information	Diagnosis of traveler's diarrhea and patient does not have fever or blood in the stool OR Diagnosis of hepatic encephalopathy and tried and failed lactulose therapy
Age Restrictions	Traveler's diarrhea - 12 years of age or older. hepatic encephalopathy - 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Traveler's diarrhea - 3 days. hepatic encephalopathy - 6 months
Other Criteria	200 mg tablet will be approved for traveler's diarrhea and 550 mg tablet will be approved for hepatic encephalopathy.

XOLAIR (S)

Products Affected

• Xolair

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of: A) moderate to severe persistent allergic asthma AND Evidence of specific allergic sensitivity confirmed by positive skin test (i.e. prick/puncture test) or blood test (i.e. radioallergosorbent test) for a specific IgE or in vitro reactivity to a perennial aeroallergen AND Pretreatment serum IgE levels greater than or equal to 30 and less than or equal to 700 IU/mL AND Symptoms are not adequately controlled with high-dose inhaled corticosteroid (ICS) plus long-acting beta2-agonist (LABA) AND patient has been adherent within a 12 month period, and is currently adherent, with asthma therapy, or B) Chronic idiopathic urticaria AND The patient has a history of itching and hives for at least 4 consecutive weeks despite titrating to an optimal dose with at least two H1 antihistamines AND Xolair will be used concurrently with an H1 antihistamine
Age Restrictions	12 years of age or older
Prescriber Restrictions	Asthma specialist (i.e., allergist, immunologist, or pulmonologist)
Coverage Duration	6 months
Other Criteria	For renewal, patient has experienced an objective response to therapy, defined as one or more of the following: Reduction in number of asthma exacerbations from baseline (i.e. asthma exacerbation requiring treatment with systemic corticosteroids or doubling of ICS dose from baseline), Improvement in forced expiratory volume in 1 second (FEV1) from baseline, Decreased use of rescue medications from baseline.

XTANDI (S)

Products Affected

• Xtandi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of metastatic castration-resistant prostate cancer AND the patient has tried and had an inadequate response, contraindication or intolerance to Zytiga.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

XYREM (S)

Products Affected

• Xyrem

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitant treatment with sedative hypnotic agents. Succinic semialdehyde dehydrogenase deficiency.
Required Medical Information	Diagnosis of narcolepsy with excessive daytime sleepiness, cataplexy or both confirmed by sleep lab evaluation (e.g., multiple sleep latency test, polysomnography) AND for patients with excessive daytime sleepiness only, patient has had a previous trial with or has a contraindication, intolerance, or allergy to modafinil, armodafinil, methylphenidate, dextroamphetamine, or mixed amphetamine salts
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For renewal, the patient had a positive response to the medication (increased sleep quality for patients with narcolepsy). Patient and physician are enrolled in the Xyrem Success Program.

YERVOY (S)

Products Affected

• Yervoy INJ 50MG/10ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of unresectable or metastatic melanoma AND If the request is for re-induction, the patient had no significant toxicity with the prior course of Yervoy AND the patient experienced progression after having stable disease for longer than three months or relapse after having a clinical response to therapy AND the prescriber is aware of the Yervoy REMS program.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	16 weeks
Other Criteria	N/A

ZALTRAP (S)

Products Affected

• Zaltrap INJ 100MG/4ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	severe hemorrhage, development of gastrointestinal perforation, compromised wound healing
Required Medical Information	Diagnosis of metastatic colon or rectal cancer AND will be used in combination with irinotecan or 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) AND disease is resistant to or has progressed following an oxaliplatin-containing regimen (e.g. 5-fluorouracil, leucovorin, and oxaliplatin [FOLFOX])
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient will be monitored for signs and symptoms of gastrointestinal bleeding and other severe bleeding. Therapy will be suspended for at least 4 weeks prior to elective surgery and not resumed for at least 4 weeks following major surgery and until the wound is fully healed. BvD Determination

ZARXIO (S)

Products Affected

Zarxio

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	A) congenital, cyclic, or idiopathic neutropenia, B) Adjunct therapy (tx) for severe febrile neutropenia (FN) and receiving myelosuppressive tx for non-myeloid malignancy with any one: Received prophylactic CSF (not Neulasta) OR Did not receive prophylactic CSF and Use as adjunct to antibiotics in high-risk pt and any one: 65 years or older, Pneumonia, Hypotension and multiorgan dysfunction (sepsis syndrome), Invasive fungal infection or clinically-documented infection, Hospitalized when developed fever, Prior FN, Severe (ANC less than 100/mcL) or anticipated prolonged (more than 10 days) neutropenia, C) Autologous peripheral-blood progenitor cell transplant for collection by leukapheresis, D) Myeloablative chemotx for non-myeloid malignancy followed by BMT, E) Acute myeloid leukemia after completing induction/consolidation chemotx, F) Acute lymphoblastic leukemia after completing first few days of chemotx of initial induction or first postremission course, G) Myelodysplastic syndrome with severe neutropenia and recurrent infection, H) Receiving radiation tx, not chemotx, and expect prolonged tx delays due to neutropenia, I) Neutropenia due to HIV infection and antiretroviral tx, J) Aplastic anemia, K) Primary prophylaxis of FN in one of the following: at least 20% FN risk based on chemotx OR 10% up to 20% risk with one of the following: 65 years or older, Poor performance status, Poor nutritional status, Previous FN, Extensive prior tx with large radiation ports, Cytopenias due to bone marrow involvement by tumor, Combined chemoradiotx, Open wounds or active infections, Other serious comorbidities (e.g., renal or liver dysfunction) OR less than 10% risk and intent is curative or adjuvant and risk for serious medical consequences, including death L) Receiving myelosuppressive chemotx for non-myeloid malignancy M) Secondary prophylaxis of FN in pt with neutropenic complication from prior chemotx cycle (where primary prophylaxis was not received)
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	12 months
Other Criteria	N/A

ZAVESCA (S)

Products Affected

• Zavesca

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of mild to moderate type 1 Gaucher disease and patient is not a candidate for enzyme replacement therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patients have been advised of the risk of fetal harm and the need for effective contraception during treatment.

ZELBORAF (S)

Products Affected

• Zelboraf

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of unresectable or metastatic melanoma and patient has positive BRAF-V600E mutation documented by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ZEPATIER (S)

Products Affected

• Zepatier

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	moderate to severe hepatic impairment (Child-Pugh Class B or C)
Required Medical Information	Diagnosis of chronic hepatitis C virus (HCV) infection AND one of the following: A) Patient has HCV genotype 1a AND Patient is treatment naïve (12 weeks) OR Patient had prior failure to peginterferon alfa plus ribavirin treatment AND Patient has been tested for the presence of NS5A resistance-associated polymorphisms AND Patient is without baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93) (12 weeks) OR Patient has baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93) AND ZEPATIER will be used in combination with ribavirin (16 weeks), OR B) Patient has HCV genotype 1b AND Patient is treatment naïve (12 weeks) OR Patient has prior failure to peginterferon alfa plus ribavirin treatment (12 weeks) OR C) Patient has HCV genotype 1a or 1b AND Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir) and Zepatier will be used in combination with ribavirin (12 weeks), OR D) Patient has HCV genotype 4 AND One of the following: Patient is treatment naïve (12 weeks) OR Patient has prior failure to peginterferon alfa plus ribavirin treatment AND medication will be used in combination with ribavirin (16 weeks)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, infectious disease specialist, or HIV specialist
Coverage Duration	As described in Required Medical information
Other Criteria	Patient is not receiving ZEPATIER in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir], Olysio [simeprevir]) AND One of the following: History of intolerance or contraindication to HARVONI therapy OR Patient is currently on ZEPATIER therapy

ZINBRYTA

Products Affected

• Zinbryta

PA Criteria	Criteria Details
Covered Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	N/A
Other Criteria	N/A

ZOHYDRO (BCBS RI)

Products Affected

• Zohydro Er ORAL C12A

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Significant respiratory depression. Acute or severe bronchial asthma or hypercarbia. Known or suspected paralytic ileus.
Required Medical Information	Diagnosis of severe pain requiring continuous, around the clock opioid long term opioid treatment AND patient who are opioid tolerant receiving for 1 week or longer at least: 60mg oral morphine/day or 25mcg fentanyl patch/hour or 30mg oxycodone/day or 8mg hydromorphone/day or 25mg oxmorphone/day AND patient has tried and failed or unable to tolerate at least two generic extended-release opioid products, such as: oxymorphone ER, morphine ER, fentanyl, tramadol ER
Age Restrictions	18 years of age or older
Prescriber Restrictions	Provider must be enrolled in the REMS program
Coverage Duration	12 months
Other Criteria	Not covered for members enrolled in a Medicare approved hospice program

ZOLINZA (S)

Products Affected

• Zolinza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of cutaneous T-cell lymphoma AND progressive, persistent or recurrent disease on or patient is not a candidate for or following at least 2 systemic therapies (e.g., bexarotene, romidepsin, etc.)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ZOMETA (S)

Products Affected

• Zometa INJ 4MG/100ML

• Zoledronic Acid INJ 4MG/100ML, 4MG/5ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Osteopenia due to hormone therapy or androgen deprivation therapy. Osteopenia or osteoporosis due to monoclonal gammopathy of uncertain significance.
Exclusion Criteria	Current treatment with Reclast.
Required Medical Information	Diagnosis of hypercalcemia of malignancy and has a corrected calcium greater than or equal to 12 mg/dL OR Diagnosis of multiple myeloma and associated bone disease (e.g., osteolytic bone lesions, bone metastases, osteopenia, etc.) OR Diagnosis of a solid tumor (e.g., breast cancer, prostate cancer that has progressed after at least one hormonal therapy (i.e. antiandrogen [bicalutamide, flutamide, nilutamide], LHRH agonist [leuprolide, goserelin], LHRH antagonists [degarelix]), kidney cancer, non-small cell lung cancer, or thyroid cancer) and patient has bone metastases and medication will be used in conjunction with standard antineoplastic therapy and medication is used for the prevention of skeletal-related events (e.g. fracture, spinal cord compression, hypercalcemia, bone pain or lesions requiring radiation or surgery) OR patient has one of the following: osteopenia (T-score -1.0 to -2.5) secondary to androgen deprivation therapy and patient has a diagnosis of breast cancer, or osteopenia or osteoporosis and patient has a diagnosis of monoclonal gammopathy of uncertain significant (MGUS).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	hypercalcemia of malignancy - 1 month. Others - 12 months

Other Criteria

Retreatment for hypercalcemia of malignancy will be considered a minimum of 7 days after initial treatment, if serum calcium does not return to normal or does not remain normal after initial treatment. For renewal of therapy for patients with bone metastases, skeletal-related events such as fractures have decreased or stabilized. For renewal of therapy for osteoporosis or osteopenia, improved or stabilized BMD, no new fractures, etc.

ZORBTIVE (S)

Products Affected

• Zorbtive

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure. Active malignancy. Active proliferative or severe non-proliferative diabetic retinopathy.
Required Medical Information	Diagnosis of short bowel syndrome AND patient is receiving specialized nutritional support (i.e. parenteral nutrition)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	4 weeks
Other Criteria	N/A

ZORTRESS (S)

Products Affected

• Zortress

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Medication is being used for: A) Prevention of kidney transplant organ rejection AND patient is at low-to-moderate immunologic risk AND member is prescribed concurrent therapy with reduced doses of cyclosporine and corticosteroids, or B) Prevention of liver transplant organ rejection AND 30 or more days have passed since the transplant procedure AND the member is prescribed concurrent therapy with reduced doses of tacrolimus and corticosteroids
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescriber is experienced in immunosuppressive therapy and management of transplant patients.
Coverage Duration	12 months
Other Criteria	Part B if transplant covered by Medicare. otherwise Part D

ZYGELIG (S)

Products Affected

• Zydelig

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The patient has one of the following diagnoses: A) chronic lymphocytic leukemia AND The medication will be used in combination with rituximab AND The patient has relapsed on at least one prior therapy (e.g., purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]) AND the patient does not have any co-morbidities that prevents the use of cytotoxic chemotherapy (i.e. severe neutropenia or thrombocytopenia, creatinine clearance less than 60 mL/minute), B) follicular lymphoma AND the patient has relapsed on at least two prior systemic therapies (e.g., rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicin], purine analogs [fludarabine]), or C) small lymphocytic lymphoma AND The patient has relapsed on at least two prior systemic therapies(e.g., rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicin], purine analogs [fludarabine])
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ZYKADIA (S)

Products Affected

• Zykadia

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer AND patient has anaplastic lymphoma kinase (ALK)-positive disease as detected by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-approved facility AND patient had an inadequate response, progressed on, or had an intolerance or contraindication to Xalkori
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ZYTIGA (S)

Products Affected

• Zytiga

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of metastatic castration-resistant prostate cancer AND Zytiga will be used in combination with prednisone
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

PART B VERSUS PART D

Products Affected

- Abelcet
- Abraxane
- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Adriamycin
- Adrucil INJ 2.5GM/50ML, 500MG/10ML
- Albuterol Sulfate INHALATION NEBU
- Alimta INJ 500MG
- Aloxi
- Amifostine
- Aminophylline
- Aminosyn
- Aminosyn 7%/electrolytes
- Aminosyn 8.5%/electrolytes

- Aminosyn II INJ 50.3MEQ/L; 695MG/100ML; 713MG/100ML; 490MG/100ML; 517MG/100ML; 350MG/100ML; 210MG/100ML; 462MG/100ML; 700MG/100ML; 735MG/100ML; 120MG/100ML; 209MG/100ML; 505MG/100ML; 371MG/100ML; 31.3MEQ/L; 280MG/100ML; 140MG/100ML; 189MG/100ML; 350MG/100ML, 61.1MEQ/L; 844MG/100ML; 865MG/100ML; 595MG/100ML; 627MG/100ML; 425MG/100ML; 255MG/100ML; 561MG/100ML; 850MG/100ML; 893MG/100ML; 146MG/100ML; 253MG/100ML; 614MG/100ML; 450MG/100ML; 33.3MEQ/L; 340MG/100ML; 170MG/100ML; 230MG/100ML; 425MG/100ML, 71.8MEQ/L; 993MG/100ML; 1018MG/100ML; 700MG/100ML; 738MG/100ML; 500MG/100ML; 300MG/100ML; 660MG/100ML; 1000MG/100ML; 1050MG/100ML; 172MG/100ML; 298MG/100ML; 722MG/100ML; 530MG/100ML; 45.3MEQ/L; 400MG/100ML; 200MG/100ML; 270MG/100ML; 500MG/100ML
- Aminosyn II 8.5%/electrolytes
- Aminosyn M
- Aminosyn-hbc
- Aminosyn-pf
- Aminosyn-pf 7%
- Aminosyn-rf
- Amiodarone Hcl INJ 50MG/ML
- Amphotericin B INJ
- Ampicillin Sodium
- Ampicillin-sulbactam
- Anzemet ORAL TABS
- Aralast Np INJ 500MG
- Arranon
- Arzerra

- Astagraf XL
- Atgam
- Azactam In Iso-osmotic Dextrose
- Azasan
- Azathioprine INJ
- Azathioprine TABS
- Azithromycin INJ
- Bethkis
- Bicnu
- Bleomycin Sulfate INJ 30UNIT
- Brovana
- Budesonide INHALATION SUSP 0.25MG/2ML, 0.5MG/2ML, 1MG/2ML
- Busulfex
- Carboplatin INJ 150MG/15ML
- Cefazolin Sodium INJ 10GM, 1GM, 1GM; 5%, 500MG
- Cefazolin Sodium/dextrose INJ 2GM;
 3%
- Cefotaxime Sodium
- Cefoxitin Sodium INJ 10GM, 1GM, 2GM
- Ceftazidime
- Ceftriaxone Sodium
- Cefuroxime Sodium
- Cefuroxime/dextrose INJ 1.5GM; 2.9%
- Cellcept Intravenous
- Cesamet
- Chlorothiazide Sodium
- Cidofovir
- Ciprofloxacin INJ 400MG/40ML
- Ciprofloxacin I.v.-in D5w
- Cisplatin INJ 100MG/100ML
- Clindamycin Phosphate INJ
- Clindamycin Phosphate Add-vantage INJ 900MG/6ML
- Clindamycin Phosphate In D5w
- Clindamycin Phosphate Pharmacy Bulk Package
- Clinimix 2.75%/dextrose 5%
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 20%

- Clinimix 4.25%/dextrose 25%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix 5%/dextrose 25%
- Clinimix E 2.75%/dextrose 10%
- Clinimix E 4.25%/dextrose 10%
- Clinisol Sf 15%
- Clolar
- Colistimethate Sodium INJ
- Cosmegen
- Cromolyn Sodium NEBU
- Cubicin
- Cubicin Rf
- Cyclophosphamide ORAL CAPS
- Cyclophosphamide ORAL TABS
- Cyclosporine INJ
- Cyclosporine ORAL CAPS
- Cyclosporine Modified
- Cytarabine INJ 500MG
- Cytarabine Aqueous
- Dacarbazine INJ 200MG
- Daunorubicin Hcl
- Daunoxome
- Decitabine
- Dexrazoxane
- Dextrose 10% Flex Container
- Dextrose 10%/nacl 0.2%
- Dextrose 10%/nacl 0.225%
- Dextrose 10%/nacl 0.45%
- Dextrose 2.5%/sodium Chloride 0.45%
- Dextrose 20%
- Dextrose 25%
- Dextrose 30%
- Dextrose 30% Partial Fill
- Dextrose 40%
- Dextrose 5%
- Dextrose 5% /electrolyte #48 Viaflex
- Dextrose 5%/nacl 0.2%
- Dextrose 5%/nacl 0.225%
- Dextrose 5%/nacl 0.3%
- Dextrose 5%/nacl 0.33%
- Dextrose 5%/nacl 0.45%

- Dextrose 5%/nacl 0.9%
- Dextrose 5%/potassium Chloride 0.15%
- Dextrose 50%
- Dextrose 70%
- Diltiazem Hcl INJ 100MG, 125MG/25ML, 125MG/25ML, 50MG/10ML
- Docefrez
- Docetaxel INJ 140MG/7ML, 160MG/8ML, 200MG/20ML, 20MG/0.5ML, 20MG/ML, 80MG/2ML, 80MG/4ML, 80MG/8ML
- Doxorubicin Hcl INJ 2MG/ML
- Doxorubicin Hcl Liposome
- Dronabinol
- Elitek
- Emend ORAL CAPS
- Engerix-b
- Envarsus Xr
- Epirubicin Hcl INJ 200MG/100ML, 50MG/25ML
- Epoprostenol Sodium
- Eraxis INJ 100MG
- Erbitux INJ 100MG/50ML
- Esomeprazole Sodium
- Ethacrynate Sodium
- Etopophos
- Etoposide INJ
- Famotidine Premixed
- Flolan
- Fluconazole In Dextrose
- Fluconazole In Nacl INJ 200MG/100ML; 0.9%, 400MG/200ML; 0.9%
- Fludarabine Phosphate
- Fluorouracil INJ 2.5GM/50ML
- Freamine Hbc 6.9%
- Freamine III
- Gablofen
- Ganciclovir INJ
- Gemcitabine Hcl INJ 1GM

- Gengraf ORAL CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hcl
- Hecoria
- Hepatamine
- Hepatasol
- Hyperrab S/d
- Hyqvia
- Idarubicin Hcl INJ 10MG/10ML
- Ifosfamide INJ 1GM
- Imipenem/cilastatin
- Imogam Rabies-ht
- Imovax Rabies (h.d.c.v.)
- Intralipid
- Ionosol-b/dextrose 5%
- Ionosol-mb/dextrose 5%
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Irinotecan INJ 100MG/5ML
- Irinotecan Hcl
- Isolyte-p/dextrose 5%
- Isolyte-s
- Istodax
- Ixempra Kit INJ 45MG
- Jevtana
- Kadcyla INJ 100MG
- Kcl 0.075%/d5w/nacl 0.45%
- Kcl 0.15%/d5w/ Nacl 0.3%
- Kcl 0.15%/d5w/lr
- Kcl 0.15%/d5w/nacl 0.2%
- Kcl 0.15%/d5w/nacl 0.225%
- Kcl 0.15%/d5w/nacl 0.9%
- Kcl 0.3%/d5w/lr IV Lac Ring
- Kcl 0.3%/d5w/nacl 0.45%
- Kcl 0.3%/d5w/nacl 0.9%
- Kepivance
- Kitabis Pak
- Labetalol Hcl INJ
- Lactated Ringers Viaflex
- Levalbuterol NEBU

- Levalbuterol Hcl INHALATION NEBU
- Levetiracetam INJ
- Levofloxacin INJ
- Levofloxacin In D5w
- Linezolid INJ 600MG/300ML
- Lioresal Intrathecal INJ 0.05MG/ML, 10MG/20ML, 10MG/5ML
- Liothyronine Sodium INJ
- Lipodox
- Lipodox 50
- Liposyn III INJ 2.5%; 30%
- Magnesium Sulfate In D5w
- Melphalan Hydrochloride
- Meropenem
- Mesna
- Methotrexate TABS
- Metoprolol Tartrate INJ
- Metronidazole INJ
- Metronidazole In Nacl 0.79%
- Mitomycin INJ 20MG
- Mitoxantrone Hcl
- Mustargen
- Mycophenolate Mofetil
- Mycophenolic Acid Dr
- Nafcillin INJ 0; 1GM/50ML
- Nafcillin Sodium
- Nebupent
- Nephramine
- Neutrexin
- Nitroglycerin INJ
- Normosol-r
- Normosol-r In D5w
- Nulojix
- Nutrilipid
- Ondansetron Hcl INJ 4MG/2ML, 4MG/2ML
- Ondansetron Hcl ORAL SOLN
- Ondansetron Hcl ORAL TABS
- Ondansetron Odt
- Oxaliplatin
- Paclitaxel INJ 300MG/50ML
- Pantoprazole Sodium INJ

- Penicillin G Potassium In Iso-osmotic Dextrose
- Pentam 300
- Perforomist
- Perjeta
- Piperacillin Sodium/ Tazobactam Sodium
- Piperacillin Sodium/tazobactam Sodium
- Piperacillin/tazobactam
- Plasma-lyte A
- Plasma-lyte-148
- Plasma-lyte-56/d5w
- Plenamine
- Potassium Chloride INJ 10MEQ/100ML, 20MEQ/100ML, 2MEQ/ML, 40MEQ/100ML
- Potassium Chloride 0.15% /nacl 0.45% Viaflex
- Potassium Chloride 0.15% D5w/nacl 0.33%
- Potassium Chloride 0.15% D5w/nacl 0.45%
- Potassium Chloride 0.15% D5w/nacl 0.45% Viaflex
- Potassium Chloride 0.15% W/nacl 0.9% Viaflex
- Potassium Chloride 0.15%/nacl 0.9%
- Potassium Chloride 0.22% D5w/nacl 0.45%
- Potassium Chloride 0.3%/ Nacl 0.9%
- Potassium Chloride 0.3%/d5w
- Premasol
- Procalamine
- Prograf INJ
- Prolastin-c
- Proleukin
- Propranolol Hcl INJ
- Prosol
- Pulmicort SUSP 1MG/2ML
- Pulmozyme
- Rabavert
- Rapamune SOLN
- Recombivax Hb

- Remodulin
- Rifampin INJ
- Ringers Injection
- Sandimmune SOLN
- Simulect INJ 20MG
- Sirolimus ORAL TABS
- Sodium Chloride INJ
- Sodium Chloride 0.45% Viaflex
- Sodium Edecrin
- Sulfamethoxazole/trimethoprim INJ
- Tacrolimus ORAL CAPS
- Teflaro
- Tetanus Toxoid Adsorbed
- Thiotepa INJ
- Thymoglobulin
- Tobi Podhaler
- Tobramycin NEBU
- Tobramycin Sulfate INJ 10MG/ML, 80MG/2ML
- Toposar
- Topotecan Hcl INJ 4MG
- Torisel
- Torsemide INJ
- Tranexamic Acid INJ
- Travasol
- Treanda INJ 100MG, 180MG/2ML, 45MG/0.5ML
- Trexall
- Trisenox

- Trophamine INJ 97MEQ/L;
 0.54GM/100ML; 1.2GM/100ML;
 0.32GM/100ML; 0; 0;
 0.5GM/100ML; 0.36GM/100ML;
 0.48GM/100ML; 0.82GM/100ML;
 1.4GM/100ML; 1.2GM/100ML;
 0.34GM/100ML; 0.48GM/100ML;
 0.68GM/100ML; 0.38GM/100ML;
 5MEQ/L; 0.025GM/100ML;
 0.42GM/100ML; 0.2GM/100ML;
 0.24GM/100ML; 0.78GM/100ML
- Twinrix
- Tygacil
- Tyvaso
- Tyvaso Refill
- Tyvaso Starter
- Valproate Sodium INJ
- Vancomycin
- Vancomycin Hcl INJ
- Velcade
- Veletri
- Ventavis
- Verapamil Hcl INJ
- Vibativ
- Vinblastine Sulfate INJ 1MG/ML
- Vincasar Pfs
- Vincristine Sulfate INJ
- Vinorelbine Tartrate INJ 50MG/5ML
- Virazole
- Zanosar
- Zemaira
- Zosyn INJ 5%; 2GM/50ML;
 0.25GM/50ML, 5%; 3GM/50ML;
 0.375GM/50ML, 5%; 4GM/100ML;
 0.5GM/100ML

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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