



Prior Authorization Criteria  
2019 PWAG  
Last Updated: 11/01/2018

## ACTEMRA SC (H)

### Products Affected

- Actemra INJ 162MG/0.9ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one nonbiologic DMARD [eg, Rheumatrex/Trexall (MTX), Arava (leflunomide), Azulfidine (sulfasalazine)]. One of the following:TF/C/I to Humira (adalimumab) OR for continuation of prior Actemra therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Trial and failure, contraindication, or intolerance to a glucocorticoid (i.e., prednisone). RA, GCA (Initial, reauth): Patient is not receiving Actemra in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
Age Restrictions	N/A
Prescriber Restrictions	RA, GCA (Initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	RA, GCA (initial, reauth): plan year
Other Criteria	RA, GCA (Reauth): Documentation of positive clinical response to Actemra therapy.

# ADCIRCA

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## Products Affected

- Adcirca

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH: plan year
<b>Other Criteria</b>	N/A

# ADEMPAS

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## Products Affected

- Adempas

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. Chronic thromboembolic pulmonary hypertension (CTEPH): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH, CTEPH: Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH, CTEPH: plan year
<b>Other Criteria</b>	N/A

# AFINITOR

## Products Affected

- Afinitor

- Afinitor Disperz

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>Advanced Neuroendocrine Tumors (NET): Diagnosis (Dx) of neuroendocrine tumors of pancreatic origin, gastrointestinal origin, lung origin, or thymic origin. Disease is unresectable, locally advanced or metastatic. Advanced Renal Cell Carcinoma: Dx of renal cell cancer. One of the following: (1) disease has relapsed or (2) both of the following: medically or surgically unresectable tumor and diagnosis of stage IV disease. One of the following: Patient with non-clear cell histology or patient with predominantly clear cell histology. Renal cell carcinoma patient with predominantly clear cell histology: Trial and failure, contraindication, or intolerance (TF/C/I) to at least one prior tyrosine kinase inhibitor therapy [eg, Nexavar (sorafenib), Sutent (sunitinib)]. Renal angiomyolipoma with tuberous sclerosis complex (TSC): Dx of renal angiomyolipoma and TSC, not requiring immediate surgery. Subependymal Giant Cell Astrocytoma (SEGA) with tuberous sclerosis (TS): Dx of SEGA associated with TS. Patient is not a candidate for curative surgical resection. Breast Cancer: Dx of hormone receptor positive, HER-2 negative breast cancer that is recurrent or metastatic. One of the following: Patient is a postmenopausal woman, patient is a premenopausal women being treated with ovarian ablation/suppression, or patient is male. One of the following: A) Both of the following: a) TF/C/I to one of the following: 1) a non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)] or 2) tamoxifen AND b) Used in combination with Aromasin (exemestane) OR B) Used in combination with Fulvestrant or Tamoxifen. For Afinitor Disperz Only: TSC Associated Partial-Onset Seizures: Dx of TSC associated partial-onset seizures. Used as adjunctive therapy.</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	NET, SEGA with TS: Prescribed by or in consultation with an oncologist or neuro-oncologist. Renal Angiomyolipoma with TSC: Prescribed by or in consultation with a nephrologist. TSC seizures: Prescribed by or in consultation with a neurologist. All other uses: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# ALECENSA

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## Products Affected

- Alecensa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Metastatic non-small cell lung cancer (NSCLC): Diagnosis of metastatic or recurrent NSCLC. Patient has anaplastic lymphoma kinase (ALK)-positive disease.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# ALOSETRON

## Products Affected

- Alosetron Hydrochloride

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Irritable bowel syndrome (IBS) (Initial): Exclude if patient is of the male gender.
<b>Required Medical Information</b>	IBS (Initial): Diagnosis of chronic severe diarrhea-predominant IBS. IBS (Reauthorization): Symptoms of IBS continue to persist. Documentation of positive clinical response to therapy.
<b>Age Restrictions</b>	IBS (Initial): 18 years and older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	IBS (Initial): 12 weeks. IBS (Reauthorization): 6 months.
<b>Other Criteria</b>	IBS (initial): Trial and failure, contraindication, or intolerance to an anti-diarrheal agent [eg, loperamide].

# ALPHA - 1 PROTEINASE INHIBITORS

## Products Affected

- Aralast Np INJ 1000MG
- Prolastin-c INJ 1000MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Alpha-1 antitrypsin (AAT) deficiency (Initial): Diagnosis of congenital AAT deficiency. One of the following: Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous) or Other rare AAT disease-causing alleles associated with serum AAT level less than 11 µmol/L [eg, Pi(Malton, Malton)]. Circulating serum concentration of AAT level less than 11 µmol/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry). Continued optimal conventional treatment for emphysema (eg, bronchodilators). Diagnosis of emphysema confirmed with pulmonary function testing. AAT deficiency (reauthorization): Documentation of positive clinical response to therapy. Continued optimal conventional treatment for emphysema (eg, bronchodilators).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	AAT deficiency (initial and reauth): plan year
<b>Other Criteria</b>	N/A



# ALUNBRIG

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## Products Affected

- Alunbrig

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic or recurrent NSCLC, tumor is anaplastic lymphoma kinase (ALK)-positive, and one of the following: a) trial and failure or intolerance to Xalkori (crizotinib) or Zykadia (ceritinib) or b) patient has recurrent brain metastases.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days

# ANADROL - 50

## Products Affected

- Anadrol-50

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acquired Aplastic Anemia: Diagnosis of acquired aplastic anemia. Congenital aplastic anemia: Diagnosis of congenital aplastic anemia (Fanconi anemia). Myelofibrosis: Diagnosis of myelofibrosis. Hypoplastic Anemia due to myelotoxic drugs: Diagnosis of hypoplastic anemia due to myelotoxic drugs. Pure Red Cell Aplasia: Diagnosis of pure red cell aplasia. Chronic Renal failure: Diagnosis of chronic renal failure.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Acquired Aplastic Anemia: One of the following: Trial and failure, contraindication, or intolerance to antilymphocyte/antithymocyte globulin (eg, Atgam, Thymoglobulin) or antilymphocyte/antithymocyte globulin plus corticosteroid treatment, OR Used in combination with antilymphocyte/antithymocyte globulin (eg, Atgam, Thymoglobulin) or antilymphocyte/antithymocyte globulin plus corticosteroids (eg, methylprednisolone, prednisone). Hypoplastic Anemia Due to Myelotoxic Drugs: Trial and failure, contraindication, or intolerance to Aranesp (darbepoetin alfa) or Epogen/Procrit (epoetin alfa). Pure Red Cell Aplasia: Trial and failure, contraindication, or intolerance to immunosuppressive therapy (eg, cyclosporine A, prednisone). Chronic Renal Failure: Trial and failure, contraindication, or intolerance to Aranesp (darbepoetin alfa) or Epogen/Procrit (epoetin alfa).

# APOKYN

## Products Affected

- Apokyn INJ 30MG/3ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Advanced Parkinson's disease diagnosis. Unable to control off symptoms with at least one adequate combination of conventional oral therapy [eg, Comtan (entacapone), Mirapex (pramipexole), Requip (ropinirole), Sinemet (carbidopa/levodopa), Stalevo (carbidopa/levodopa/entacapone), Symmetrel (amantadine), Tasmar (tolcapone)]. Used in combination with a non-5HT3 antagonist antiemetic [eg, Tigan (trimethobenzamide) 300 mg PO TID] for initial therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Apokyn will only be approved for intermittent subcutaneous injection.

# APREPITANT

## Products Affected

- Aprepitant

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acute Chemotherapy-induced Nausea and Vomiting (CINV): Patient is currently receiving moderately or highly emetogenic chemotherapy. Patient is concurrently on both corticosteroid [eg, Decadron (dexamethasone)] and 5-HT <sub>3</sub> receptor antagonist [eg, Aloxi (palonosetron), Anzemet (dolasetron), Kytril (granisetron), Zofran (ondansetron)]. Delayed Chemotherapy-induced Nausea and Vomiting Prevention: Patient is currently receiving highly emetogenic chemotherapy and corticosteroid [eg, Decadron (dexamethasone)], or patient is receiving an anthracycline [eg, Adriamycin (doxorubicin), Ellence (epirubicin)] and Cytoxan (cyclophosphamide), or patient is currently receiving moderately emetogenic chemotherapy and was given Emend (oral or IV) on day 1 of chemotherapy. Postoperative Nausea and Vomiting (PONV): For the prevention of postoperative nausea and vomiting when administered prior to the induction of anesthesia.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Acute CINV, Delayed CINV: plan year. PONV: 1 month
<b>Other Criteria</b>	Subject to Part B vs. Part D review.

# ARANESP

## 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 medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>Anemia due to Chronic Kidney Disease (CKD) (Initial): Diagnosis of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) within 30 days of request. The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. (Reauth): Diagnosis of CKD. Most recent or average (avg) Hct over 3 mo is 33% or less (Hgb 11 g/dL or less) for patients on dialysis, without ESRD OR Most recent or average (avg) Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis OR Most recent or average (avg) Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Anemia w/ chemo (Initial): Other causes of anemia ruled out. Anemia w/ labs (Hct less than 30%, Hgb less than 10 g/dL) within prior 2 weeks of request. Cancer is non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for minimum of 2 months, or anemia caused by cancer chemo. (Reauth): Anemia by labs (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-tx level. Patient is concurrently on chemo, or will receive concomitant chemo for minimum of 2 months, or anemia is caused by cancer chemo. Anemia in MDS (Init): Diagnosis of MDS. Serum erythropoietin 500 mU/mL or less, or transfusion dependent MDS. (Reauth): Most recent or avg Hct over 3 months was 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level.</p>

<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	CKD(Init): 6 mo. CKD(reauth):plan yr. Chemo(init, reauth): 3 mo. MDS(init): 3 mo,(reauth): plan yr
<b>Other Criteria</b>	ESRD patients: Coverage is excluded under Medicare Part D for patients with ESRD on dialysis for any indication related or unrelated to treatment of ESRD since the payment for the drug is included in the ESRD PPS payment bundle. NON-ESRD PATIENTS for the following indications: Anemia in cancer patients on chemotherapy (init, reauth): Will not be approved if patient is not receiving cancer chemotherapy. Off-label uses (except Anemia in Myelodysplastic Syndrome (MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.CKD (init, reauth), Chemo (init), MDS (init): Verify Fe eval for adequate Fe stores.

# ARCALYST

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## Products Affected

- Arcalyst

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: Diagnosis of Cryopyrin-Associated Period Syndromes (CAPS), Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	CAPS (initial, reauth): plan year
<b>Other Criteria</b>	N/A

# AURYXIA

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## Products Affected

- Auryxia

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Exclude if used for iron deficiency anemia in chronic kidney disease (CKD) not on dialysis.
<b>Required Medical Information</b>	Hyperphosphatemia in chronic kidney disease: Diagnosis of hyperphosphatemia. Patient has chronic kidney disease (CKD). Patient is on dialysis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A



# BACTROBAN NASAL

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## Products Affected

- Bactroban Nasal

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Methicillin resistant Staphylococcus aureus infection, nasal colonization: For eradication of nasal colonization with methicillin-resistant S. aureus. Used as part of a comprehensive infection control program during institutional outbreaks of infections with methicillin-resistant S. aureus.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# BENLYSTA

## Products Affected

- Benlysta INJ 200MG/ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Systemic Lupus Erythematosus (SLE): (Initial): Diagnosis of active SLE. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL). Currently receiving at least one standard of care treatment for active SLE (eg, antimalarials [eg, Plaquenil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine)]). (Reauthorization): Documentation of positive clinical response to Benlysta therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	SLE (initial): Prescribed by or in consultation with a rheumatologist
<b>Coverage Duration</b>	SLE (initial and reauth): 6 months
<b>Other Criteria</b>	N/A

# BERINERT

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## Products Affected

- Berinert

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# BEXAROTENE

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## Products Affected

- Bexarotene

- Targretin GEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cutaneous T-cell lymphoma (CTCL): Diagnosis of cutaneous T-cell lymphoma (CTCL).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# BOSULIF

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## Products Affected

- Bosulif

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of chronic myelogenous/myeloid leukemia (CML).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# CABOMETYX

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## Products Affected

- Cabometyx

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renal cell carcinoma (RCC): Diagnosis of RCC.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RCC: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# CALQUENCE

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## Products Affected

- Calquence

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL) AND patient has received at least one prior therapy for MCL
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

## CARAC (BRAND)

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### Products Affected

- Carac

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Trial and failure or intolerance to generic topical fluorouracil 0.5% cream.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A



# CAYSTON

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## Products Affected

- Cayston

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cystic Fibrosis (CF): Diagnosis of CF and lung infection with positive culture demonstrating <i>Pseudomonas aeruginosa</i> infection.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# CHOLBAM

## Products Affected

- Cholbam

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) Cholbam will be used as an adjunctive treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial: Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.
<b>Coverage Duration</b>	Initial: 3 months Reauth: Plan year
<b>Other Criteria</b>	All uses (reauth): documentation of positive clinical response to Cholbam therapy.

# CLONIDINE ER

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## Products Affected

- Clonidine Hcl Er

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of attention deficit hyperactivity disorder (ADHD).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# COMETRIQ

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## Products Affected

- Cometriq

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medullary Thyroid Cancer (MTC): Diagnosis of one of the following: metastatic medullary thyroid cancer (MTC).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# CORLANOR

## Products Affected

- Corlanor

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic heart failure (CHF) (initial): Diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Patient has a left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm. Patient has a resting heart rate of greater than or equal to 70 beats per minute. One of the following: patient is on a beta-blocker at a maximally tolerated dose, or patient has a contraindication or intolerance to beta-blocker therapy. Patient has been hospitalized for worsening HF in the previous 12 months. Trial and failure, contraindication, or intolerance to maximally tolerated doses of an ACE inhibitor or ARB.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	CHF (initial): Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	Initial, reauth: plan year
<b>Other Criteria</b>	CHF (reauth): Documentation of positive clinical response to Corlanor therapy.

## COSENTYX (H)

### Products Affected

- Cosentyx

- Cosentyx Sensoready Pen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Trial and failure, contraindication, or intolerance to Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: Trial and failure, contraindication, or intolerance to Humira (adalimumab), OR for continuation of prior Cosentyx therapy. All indications (Initial, reauth): Patient is not receiving Cosentyx in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. Psoriatic Arthritis (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. AS (initial): Prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	Initial and reauth: plan year
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Cosentyx therapy.

# COTELLIC

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## Products Affected

- Cotellic

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Melanoma: Diagnosis of unresectable or metastatic melanoma. Disease is positive for BRAF V600E or V600K mutation. Used in combination with Zelboraf (vemurafenib).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# CRINONE

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## Products Affected

- Crinone

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	All indications: Excluded if for fertility uses.
<b>Required Medical Information</b>	Secondary amenorrhea: Diagnosis of secondary amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	N/A



# DALIRESP

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## Products Affected

- Daliresp

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic Obstructive Pulmonary Disease (COPD): (Initial) Diagnosis of moderate to very severe COPD. COPD is associated with chronic bronchitis. History of COPD exacerbations which required the use of systemic corticosteroids, antibiotics, or hospital admission. Trial and failure, intolerance, or contraindication to two prior therapies for COPD.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial, reauth: plan year
<b>Other Criteria</b>	COPD (reauth): Documentation of positive clinical response to Daliresp therapy.

# DEGARELIX

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## Products Affected

- Firmagon

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prostate Cancer: Diagnosis of advanced prostate cancer.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# DICLOFENAC GEL 1%

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## Products Affected

- Diclofenac Sodium GEL 1%

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# DICLOFENAC GEL 3%

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## Products Affected

- Diclofenac Sodium GEL 3%

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Actinic Keratosis (initial): Diagnosis of Actinic Keratosis. Actinic Keratosis (reauthorization): Documentation of positive clinical response to diclofenac sodium 3% topical gel therapy. At least 30 days have elapsed since cessation of diclofenac sodium 3% topical gel therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	90 days
<b>Other Criteria</b>	N/A

# DOXEPIN TOPICAL

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## Products Affected

- Doxepin Hydrochloride CREA
- Prudoxin

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of moderate pruritus. Patient has atopic dermatitis or lichen simplex chronicus. Trial and failure, contraindication, or intolerance to at least one medium potency topical corticosteroid, or is not a candidate for topical corticosteroids (e.g., treatment is on face, axilla, or groin).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	N/A

# DRONABINOL

## Products Affected

- Dronabinol

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	CINV: 6 months. AIDS anorexia: 3 months.
<b>Other Criteria</b>	Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving chemotherapy. Trial and failure, contraindication, or intolerance (TF/C/I) to 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). TF/C/I to one of the following: Ativan (lorazepam), Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Phenergan (promethazine), Reglan (metoclopramide), Zyprexa (olanzapine).

# EGRIFTA

## Products Affected

- Egrifta INJ 1MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>(Initial): Diagnosis of HIV-associated lipodystrophy. Waist-circumference greater than or equal to 95 cm (37.4 inches) in men, or greater than or equal to 94 cm (37 inches) for women. Waist-to-hip ratio greater than or equal to 0.94 for men, or greater than or equal to 0.88 for women. Body mass index (BMI) greater than 20 kg/m<sup>2</sup>. Fasting blood glucose (FBG) levels less than or equal to 150 mg/dL (8.33 mmol/L). Patient has been on a stable regimen of antiretrovirals (eg, NRTIs, NNRTI, Protease Inhibitors, Integrase Inhibitors) for at least 8 weeks.</p> <p>(Reauth): Documentation of clinical improvement (eg, improvement in VAT, decrease in waist circumference, belly appearance) while on Egrifta therapy.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial and reauth: 6 months
<b>Other Criteria</b>	N/A

## EMEND (SUSPENSION)

### Products Affected

- Emend SUSR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acute Chemotherapy-induced Nausea and Vomiting (CINV): Patient is currently receiving moderately or highly emetogenic chemotherapy. Patient is concurrently on both corticosteroid [eg, Decadron (dexamethasone)] and 5-HT <sub>3</sub> receptor antagonist [eg, Aloxi (palonosetron), Anzemet (dolasetron), Kytril (granisetron), Zofran (ondansetron)]. Delayed Chemotherapy-induced Nausea and Vomiting Prevention: Patient is currently receiving highly emetogenic chemotherapy and corticosteroid [eg, Decadron (dexamethasone)], or patient is receiving an anthracycline [eg, Adriamycin (doxorubicin), Ellence (epirubicin)] and Cytosan (cyclophosphamide), or patient is currently receiving moderately emetogenic chemotherapy and was given Emend (oral or IV) on day 1 of chemotherapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Acute CINV, Delayed CINV: Plan Year
<b>Other Criteria</b>	Subject to Part B vs. Part D review.



# EPCLUSA

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## Products Affected

- Epclusa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C virus. Patient is not receiving Epclusa in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
<b>Coverage Duration</b>	12 to 24 weeks. (84 - 168 tabs) Criteria applied consistent with current AASLD/IDSA guideline
<b>Other Criteria</b>	N/A

# EPOETIN ALFA

## Products Affected

- Procrit

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>Anemia due to Chronic Kidney Disease (CKD) (Initial): Diagnosis (dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) within 30 days of request. The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. (Reauth): Diagnosis of CKD. Most recent or average (avg) Hct over 3 months is 33% or less (Hgb 11 g/dL or less) for patients on dialysis, without ESRD OR Most recent or average (avg) Hct over 3 months is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis OR Most recent or average (avg) Hct over 3 months is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level.</p> <p>Anemia w/ HIV (Initial): Anemia by labs (Hgb less than 12 g/dL or Hct less than 36%) within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level.</p> <p>Anemia with chemo (Initial): Other causes of anemia ruled out. Anemia with labs (Hct less than 30%, Hgb less than 10 g/dL) within prior 2 weeks of request. Cancer is non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for minimum of 2 mos, or anemia caused by cancer chemo. (Reauth): Anemia by labs (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 wks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for minimum of 2 months, or anemia is caused by cancer chemo.</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A

<b>Coverage Duration</b>	CKD, HIV(Init): 6 mo. (reauth):plan yr. Chemo(init, reauth): 3 mo. MDS(init): 3 mo,(reauth): plan yr
<b>Other Criteria</b>	<p>Anemia in Myelodysplastic Syndrome (MDS) (Init): Diagnosis of MDS. Serum erythropoietin 500 mU/mL or less, or transfusion dependent MDS. (Reauth): Most recent or avg Hct over 3 months was 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. ESRD patients: Coverage is excluded under Medicare Part D for patients with ESRD on dialysis for any indication related or unrelated to treatment of ESRD since the payment for the drug is included in the ESRD PPS payment bundle. NON-ESRD PATIENTS for the following indications: Anemia in cancer patients on chemotherapy (init, reauth): Will not be approved if patient is not receiving cancer chemotherapy. Off-label uses (except Anemia in MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.CKD (init, reauth), Chemo (init), MDS (init): Verify Fe eval for adequate Fe stores.</p>

# ERIVEDGE

## Products Affected

- Erivedge

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Metastatic basal cell carcinoma (BCC): Diagnosis of metastatic basal cell carcinoma. Advanced basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma. One of the following: Cancer has recurred following surgery, Patient is not a candidate for surgery, or Patient is not a candidate for radiation.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Metastatic and Advanced BCC: Prescribed by or in consultation with a dermatologist or oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# ERLEADA

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## Products Affected

- Erleada

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-metastatic castration-resistant prostate cancer (NM-CRPC): Diagnosis of non-metastatic, castration-resistant (chemical or surgical) prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog OR 2) Patient received a bilateral orchiectomy. Trial and failure or intolerance to Xtandi (enzalutamide).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days

# ESBRIET

## Products Affected

- Esbriet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF, defined as exclusion of other known causes of interstitial lung disease and either the presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF in patients not subjected to lung biopsy, or HRCT and surgical lung biopsy pattern revealing IPF or probable IPF in patients subjected to a lung biopsy. IPF (reauth): Documentation of positive clinical response to therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	(initial): Prescribed by a pulmonologist.
<b>Coverage Duration</b>	(initial, reauth): plan year
<b>Other Criteria</b>	(initial, reauth): Not used in combination with Ofev.

# EXJADE

## Products Affected

- Exjade

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Chronic Iron Overload due to Blood Transfusions (initial): Diagnosis of chronic iron overload (eg, sickle cell anemia, thalassemia, etc.) due to blood transfusion. Patient has blood transfusion of at least 100 mL/kg of packed red blood cells (eg, at least 20 units of packed red blood cells for a 40-kg person or more in individuals weighing more than 40 kg) prior to initiation of treatment with deferasirox. Patient has serum ferritin levels consistently greater than 1000 mcg/L prior to initiation of treatment with deferasirox. Trial and failure, or intolerance to parenteral deferoxamine mesylate therapy. Chronic Overload in non-transfusion dependent thalassemia syndromes (initial): Diagnosis of chronic iron overload in non-transfusion dependent thalassemia syndrome. Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with deferasirox. Patient has serum ferritin levels consistently more than 300 mcg/L prior to initiation of treatment with deferasirox. Chronic Iron Overload due to Blood Transfusions, Chronic Overload in non-transfusion dependent thalassemia syndromes (reauthorization): Documentation of positive clinical response to Exjade therapy.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Chronic Iron Overload due to Blood Transfusions, Chronic Overload in non-transfusion dependent thalassemia syndromes (initial): Prescribed by a hematologist/oncologist or hepatologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# FARYDAK

## Products Affected

- Farydak

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with one of the following: 1) Velcade (bortezomib) and dexamethasone OR 2) Kyprolis (carfilzomib). Patient has received at least two prior treatment regimens which included both of the following: Velcade (bortezomib) and an immunomodulatory agent (eg, Revlimid (lenalidomide), Thalomid (thalidomide)).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.



## FENTANYL (PREFERRED)

### Products Affected

- Fentanyl Citrate Oral Transmucosal

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cancer pain: Chart documentation provided reflecting oral transmucosal fentanyl will be used to manage pain related to an active cancer diagnosis. At least a one week history of one of the following medications to demonstrate tolerance to opioids: morphine sulfate at doses of greater than or equal to 60 mg/day, fentanyl transdermal patch at doses greater than or equal to 25 µg/hr, oxycodone at a dose of greater than or equal to 30 mg/day , oral hydromorphone at a dose of greater than or equal to 8 mg/day, oral oxymorphone at a dose of greater than or equal to 25 mg/day, an alternative opioid at an equianalgesic dose (eg, oral methadone greater than or equal to 20 mg/day). The patient is currently taking a long-acting opioid around the clock for cancer pain
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, pain specialist, hematologist, hospice care specialist, or palliative care specialist.
Coverage Duration	Plan year
Other Criteria	N/A

# FERRIPROX

## Products Affected

- Ferriprox

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Transfusional iron overload due to thalassemia syndromes: Diagnosis of transfusional iron overload due to thalassemia syndromes. Absolute neutrophil count (ANC) greater than $1.5 \times 10^9/L$ . One of the following: A) Trial and failure, defined as serum ferritin greater than 2,500 mcg/L, to Desferal (deferroxamine), Exjade (deferasirox) or Jadenu (deferasirox) OR B) History of contraindication or intolerance to Desferal (deferroxamine), Exjade (deferasirox) or Jadenu (deferasirox).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	All uses (reauth): Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline. ANC greater than $1.5 \times 10^9/L$ .

# FIRAZYR

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## Products Affected

- Firazyr

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# FORTEO

## Products Affected

- Forteo INJ 600MCG/2.4ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia: Diagnosis of one of the following: a) postmenopausal osteoporosis or osteopenia or b) primary or hypogonadal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones (e.g., Forteo [teriparatide], Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	All indications: plan year (up to 24 months per lifetime).

<b>Other Criteria</b>	Glucocorticoid-Induced Osteoporosis: Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: 1) BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site), or 2) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions, or 3) History of one of the following fractures resulting from minimal trauma: vertebral compression fx, fx of the hip, fx of the distal radius, fx of the pelvis, or fx of the proximal humerus. TF/C/I to one bisphosphonate (e.g., alendronate). Treatment duration of parathyroid hormones (e.g., Forteo (teriparatide), Tymlos (abaloparatide)) has not exceeded a total of 24 months during the patient's lifetime.
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# GATTEX

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## Products Affected

- Gattex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of short bowel syndrome. Patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 consecutive months.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# GILOTRIF

## Products Affected

- Gilotrif

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. One of the following: 1) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by an FDA-approved test OR 2) squamous disease progressing after previous platinum-based chemotherapy OR 3) tumors are positive for a known sensitizing EGFR mutation.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	NSCLC: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

## GROWTH HORMONES (PREFERRED)

### Products Affected

- Genotropin

- Genotropin Miniquick

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D. Transition Phase Adolescent Patients (TPAP)
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)].</p> <p>PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal.</p> <p>GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean).</p> <p>TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender.</p> <p>SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing.</p> <p>GFCRI(initial): ped grwth failure dx assoc w/CRI.</p> <p>ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age.</p> <p>PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs.</p> <p>PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist



<b>Coverage Duration</b>	All indications (initial, reauth): Plan year
<b>Other Criteria</b>	<p>AGHD(initial):dx of AGHD as a result of clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/corresponding peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IGF-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(initial,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrozole,letrozole) or androgens(eg,testosterone cypionate). AGHD,IGHDA(reauth):evidence of ongoing monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3). IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).</p>

# HARVONI

## Products Affected

- Harvoni

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD/IDSA guideline. ALL (including patients with genotype 5 or 6 infection AND decompensated cirrhosis): A) Diagnosis of chronic hepatitis C virus AND B) Patient is not receiving Harvoni in combination with another HCV direct acting antiviral agent [eg, Sovaldi (sofosbuvir)].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
<b>Coverage Duration</b>	12 to 24 weeks (84-168 tabs). Criteria will be applied consistent with current AASLD/IDSA guideline
<b>Other Criteria</b>	N/A

# HETLIOZ

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## Products Affected

- HetlioZ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-24-hour sleep-wake disorder: Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernycthemeral syndrome).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Patient is totally blind (has no light perception).

# HEXALEN

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## Products Affected

- Hexalen

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of ovarian cancer AND cancer has progressed or recurred following first-line treatment with a cisplatin or alkylating agent-based combination.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# HUMIRA

## Products Affected

- Humira
- Humira Pediatric Crohns Disease Starter Pack
- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-ps/uv Starter

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>Rheumatoid Arthritis (RA)(Initial): Diagnosis (dx) of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (MTX) (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Juvenile Idiopathic Arthritis (JIA)(Initial): dx of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or MTX (Rheumatrex/Trexall). Psoriatic Arthritis (PsA)(Initial): dx of active PsA. Plaque psoriasis (PSO)(Initial): dx of moderate to severe chronic PSO. Ankylosing Spondylitis (AS) (Initial): dx of active AS. TF/C/I to two NSAIDs. Crohn's Disease (CD)(Initial): dx of moderately to severely active CD. TF/C/I to one of the following conventional therapies: 6-mercaptopurine (6-MP), Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), MTX (Rheumatrex/Trexall), or failure (ie, lost response) or intolerance to Remicade (infliximab). Ulcerative Colitis (UC)(Initial): dx of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-MP, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa(Initial): dx of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis(initial): dx of non-infectious uveitis classified as intermediate, posterior, or panuveitis. All indications (initial,reauth): Patient is not receiving Humira in combination with a biologic DMARD [eg,Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)].</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	RA, AS, JIA: (Initial) Prescribed by or in consultation with a rheumatologist. PsA: (Initial) Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS: (Initial) Prescribed by or in consultation with a dermatologist. CD, UC: (Initial) Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with a rheumatologist or an ophthalmologist.
<b>Coverage Duration</b>	UC: (Initial) 12 wks, (reauth) plan year. Other indications (initial/reauth): plan year.
<b>Other Criteria</b>	RA, JIA, PsA, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.

# IBRANCE

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## Products Affected

- Ibrance

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Breast cancer: Diagnosis of breast cancer. Disease is a) locally advanced, metastatic, recurrent, or Stage IV
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# ICLUSIG

## Products Affected

- Iclusig

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>Chronic Myelogenous / Myeloid Leukemia (CML): Diagnosis of chronic myelogenous/myeloid leukemia (CML). One of the following: a) The patient is unable to take or has failed treatment with two or more alternative tyrosine kinase inhibitors (TKI) [eg, Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib)], or b) confirmed documentation of T315I mutation. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL). One of the following: a) the patient is unable to take or has failed treatment with two or more alternative tyrosine kinase inhibitors (TKI) [eg, Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib)], or b) confirmed documentation of T315I mutation, or c) used in combination with an induction regimen not previously used.</p>
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# IDHIFA

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## Products Affected

- Idhifa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. AML is isocitrate dehydrogenase-2 (IDH2) mutation-positive.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# IMATINIB

## Products Affected

- Imatinib Mesylate

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic Myelogenous/Myeloid Leukemia (CML): Diagnosis of CML (CML). Acute Lymphoblastic Leukemia (ALL): Diagnosis of Philadelphia chromosome positive ALL (Ph+ALL). Myelodysplastic/myeloproliferative disease (MDS/MPD): Diagnosis of MDS/MPD associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. Aggressive systemic mastocytosis (ASM): Diagnosis of ASM. Patient is without the D816V c-Kit mutation or c-Kit mutational status unknown. Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL): Diagnosis of at least one of the following: HES or CEL. Dermatofibrosarcoma protuberans (DFSP): Diagnosis of DFSP. Gastrointestinal Stromal Tumors (GIST): Diagnosis of GIST.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# IMBRUVICA

## Products Affected

- Imbruvica

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Mantle cell lymphoma (MCL): Diagnosis of MCL and patient has received at least one prior therapy for MCL (eg, Rituxan [rituximab]). Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal zone lymphoma (MZL): Diagnosis of MZL and patient has received at least one prior anti-CD20-based therapy for MZL [e.g., Rituxan (rituximab), Zevalin (ibritumomab), Gazyva (obinutuzumab, etc.)]. Chronic Graft Versus Host Disease (cGVHD): Diagnosis of cGVHD AND trial and failure of at least one other systemic therapy (e.g., corticosteroids, mycophenolate, etc.).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	All uses (except cGVHD): Prescribed by or in consultation with a hematologist/oncologist. cGVHD: Prescribed by or in consultation with a hematologist, oncologist, or physician experienced in the management of transplant patients.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# IMMUNE GLOBULIN

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## Products Affected

- Bivigam INJ 10GM/100ML
- Carimune Nanofiltered INJ 6GM
- Flebogamma Dif INJ 10%
- Gammagard Liquid INJ 2.5GM/25ML
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked INJ 1GM/10ML
- Gammaplex INJ 10GM/100ML; 0, 10GM/200ML, 20GM/200ML, 5GM/50ML
- Gamunex-c INJ 1GM/10ML
- Octagam INJ 1GM/20ML, 2GM/20ML
- Privigen INJ 20GM/200ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A

<b>Required Medical Information</b>	<p>Primary immunodeficiency syndrome (PIS): patients with PIS. Idiopathic Thrombocytopenic Purpura (ITP): diagnosis (dx) of ITP. Documented (doc) platelet count of less than <math>50 \times 10^9/L</math>. Kawasaki disease (KD): dx of KD. B-cell Chronic Lymphocytic Leukemia (CLL): dx of B-Cell CLL. Doc hypogammaglobulinemia (IgG less than 500mg/dL) or history of bacterial infections associated with B-cell CLL. Bone Marrow Transplant (BMT): Confirmed allogeneic BMT within the last 100 days. Doc severe hypogammaglobulinemia (IgG less than 400 mg/dL). HIV:dx of HIV. 13 years of age or less. Doc hypogammaglobulinemia (IgG less than 400 mg/dL) or functional antibody deficiency demonstrated by poor specific antibody titers or recurrent bacterial infections. Guillain-Barre Syndrome (GBS) initial: dx of GBS. severe disease requiring aid to walk. Onset of neuropathic symptoms in the last 4 weeks. Myasthenia Gravis (MG): dx of generalized MG. Evidence of myasthenic exacerbation, defined by 1 of the following sx's in the last month: difficulty swallowing, acute respiratory failure, or major functional disability responsible for the discontinuation of physical activity. Concomitant immunomodulator therapy (tx)(eg, azathioprine, cyclosporine), unless contraindicated, will be used for long-term management of MG. Dermatomyositis and Polymyositis (D/P) initial: dx of dermatomyositis or polymyositis. Trial and failure, contraindication or intolerance (TF/C/I) to immunosuppressive tx (eg corticosteroids, methotrexate, azathioprine, cyclophosphamide). Stiff person syndrome (SPS) initial:dx of SPS. TF/C/I to GABAergic medication (eg, baclofen). TF/C/I to immunosuppressive tx (eg, azathioprine, corticosteroids). Lambert-Eaton myasthenic syndrome (LEMS) initial: dx of LEMS. TF/C/I to immunomodulator monotherapy (eg, azathioprine, corticosteroids). Concomitant immunomodulator tx (eg, azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	MG: Prescribed by a neurologist.
<b>Coverage Duration</b>	KD: 1 mo. GBS,CIDP (initial), MG: 3 mo. ITP: 6 mo. CIDP,GBS (reauth), other uses: plan year.

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**Other Criteria**

Subject to Part B vs. Part D review. PIS: Clinically significant functional deficiency of humoral immunity as evidenced by doc failure to produce antibodies to specific antigens or hx of significant recurrent infxns. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) initial: dx of CIDP confirmed by: (1) progressive sx's present for at least 2 mo, (2) symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor impairment of more than 1 limb, OR Progressive or relapsing sensory impairment of more than 1 limb, (3) Electrophysiologic findings when 3 of the following 4 criteria are present: Partial conduction block of 1 or more motor nerve, Reduced conduction velocity of 2 or more motor nerves, Prolonged distal latency of 2 or more motor nerves, Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves. Multifocal motor neuropathy (MMN) initial: dx of MMN as confirmed by all of the following: (1) weakness with slowly progressive or stepwise progressive course over at least 1 month, (2) asymmetric involvement of 2 or more nerves, AND (3) absence of motor neuron signs and bulbar signs. CIDP, MMN reauth: documentation of positive clinical response to tx as measured by an objective scale [eg, Rankin, Modified Rankin, Medical Research Council (MRC) scale]. Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect. Relapsing remitting Multiple Sclerosis (MS) initial: dx of relapsing remitting form of MS (RRMS). Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin tx. TF/c/I to 2 of the following: Aubagio (teriflunomide), Betaseron (interferon beta-1b), Avonex (interferon beta-1a), Copaxone (glatiramer acetate), Rebif (interferon beta-1a), Tysabri (natalizumab), Tecfidera (dimethyl fumarate), Extavia (interferon beta-1b), Gilenya (Fingolimod). RRMS reauth: The prescriber maintains and provides chart documentation of the patient's evaluation, including all of the following: findings of interval examination including neurological deficits incurred, and assessment of disability (eg, Expanded Disability Status Score [EDSS], Functional Systems Score [FSS], Multiple Sclerosis Functional Composite [MSFC], Disease Steps [DS]). Stable or improved disability score (eg, EDSS, FSS, MSFC, DS). Documentation of decreased number of relapses since starting immune globulin tx. Dx continues to be the relapsing-remitting form of MS. Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect. GBS, D/P, SPS, LEMS reauth: Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect.

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# INLYTA

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## Products Affected

- Inlyta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Advanced Renal Cell Carcinoma: Diagnosis of renal cell cancer. One of the following: (1) disease has relapsed or (2) both of the following: medically or surgically unresectable tumor and diagnosis of stage IV disease.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# INSULIN - LIKE GROWTH FACTOR

## Products Affected

- Increlex

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Initial therapy: IGF-1 deficiency: Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). Documentation of open epiphyses on last bone radiograph. The patient will not be treated with concurrent GH therapy. GH gene deletion: Diagnosis of growth hormone gene deletion who have developed neutralizing antibodies to GH. Documentation of open epiphyses on last bone radiograph. The patient will not be treated with concurrent GH therapy. Reauthorization: Documentation of positive clinical response to therapy. Both of the following: (1) Expected adult height is not obtained and (2) Documentation of expected adult height goal
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: plan year
Other Criteria	N/A



# INTRON - A

## Products Affected

- Intron A

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Diagnosis of chronic hepatitis C, patient without decompensated liver disease, patients who have not previously been treated with interferon, and one of the following - 1) used in combination with ribavirin or 2) contraindication or intolerance to ribavirin. Metastatic renal cell carcinoma (RCC): diagnosis of metastatic RCC, used in combination with Avastin (bevacizumab). Other: diagnosis of condylomata acuminata (genital or perianal), diagnosis of hairy cell leukemia, diagnosis of AIDS-related Kaposi's sarcoma, diagnosis of malignant melanoma, diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma, as maintenance therapy for the treatment of multiple myeloma.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RCC: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	HepB, HepC: 48 wks. Condylomata acuminata (genital or perianal): 6 wks. Other: 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# IRESSA

## Products Affected

- Iressa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC, and One of the following: tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions or tumors are positive for EGFR exon 21 (L858R) substitution mutations or tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# ISOTRETINOIN

## Products Affected

- Claravis

- Isotretinoin CAPS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	(initial): Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy OR diagnosis of treatment resistant acne. Trial and failure, contraindication or intolerance to an adequate trial on two of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin),] b) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)], c) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]. Retreatment (Reauthorization): After greater than or equal to 2 months off therapy, persistent or recurring severe recalcitrant nodular acne is still present. Dose Titration (Reauthorization): Confirmation that the total cumulative dose for total duration of therapy is less than 150 mg/kg.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Reauth: Retreatment - 6 months, Dose Titration - 1 month
<b>Other Criteria</b>	N/A

## ITRACONAZOLE (CAPSULES)

### Products Affected

- Itraconazole CAPS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Systemic Fungal Infections: Diagnosis of blastomycosis, histoplasmosis, or aspergillosis. Onychomycosis (initial): Diagnosis of fingernail or toenail onychomycosis confirmed by one of the following: KOH test, fungal culture, or nail biopsy. (retreatment): One of the following: Nine months has elapsed since completion of initial therapy for toenail onychomycosis or three months have elapsed since completion of initial therapy for fingernail onychomycosis. Documentation of positive clinical response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Systemic Fungal infxns: plan year. Onychomycosis: (Fingernail) 2 mo. (Toenail) 3 mo.
Other Criteria	N/A

# JADENU

## Products Affected

- Jadenu

- Jadenu Sprinkle

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic Iron Overload due to Blood Transfusions (initial): Diagnosis of chronic iron overload (eg, sickle cell anemia, thalassemia, etc.) due to blood transfusion. Patient has blood transfusion of at least 100 mL/kg of packed red blood cells (eg, at least 20 units of packed red blood cells for a 40-kg person or more in individuals weighing more than 40 kg) prior to initiation of treatment with deferasirox. Patient has serum ferritin levels consistently greater than 1000 mcg/L prior to initiation of treatment with deferasirox. Trial and failure, or intolerance to parenteral deferoxamine mesylate therapy. Chronic Overload in non-transfusion dependent thalassemia syndromes (initial): Diagnosis of chronic iron overload in non-transfusion dependent thalassemia syndrome. Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with deferasirox. Patient has serum ferritin levels consistently more than 300 mcg/L prior to initiation of treatment with deferasirox. Chronic Iron Overload due to Blood Transfusions, Chronic Overload in non-transfusion dependent thalassemia syndromes (reauthorization): Documentation of positive clinical response to therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial authorization: Prescribed by a hematologist/oncologist or hepatologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# JAKAFI

## Products Affected

- Jakafi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Myelofibrosis: One of the following: Primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera and trial and failure, contraindication, or intolerance to hydroxyurea.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Myelofibrosis, polycythemia vera: Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	Myelofibrosis, polycythemia vera: 6 months
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

## JUXTAPID (PREFERRED)

### Products Affected

- Juxtapid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient has been receiving at least 12 consecutive weeks of ONE LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. 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 LDL-C greater than or equal to 130 mg/dL without ASCVD. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (eg, clarithromycin).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.
<b>Coverage Duration</b>	HoFH (initial): 6 months. (reauth): plan year

<b>Other Criteria</b>	HoFH (reauthorization): 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). Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior Juxtapid therapy) while on Juxtapid therapy. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (eg, clarithromycin).
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# KALYDECO

## Products Affected

- Kalydeco

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Submission of laboratory records confirming patient has one of the following mutations in the CFTR gene: A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, G178R, G551D, G551S, G1069R, G1244E, G1349D, K1060T, L206W, P67L, R74W, R117C, R117H, R347H, R352Q, R1070Q, R1070W, S549N, S549R, S945L, S977F, S1251N, S1255P, 711+3A-G, 2789+5G-A, 3272-26A-G, or 3849+10kbC-T. (Reauthorization): Documentation of one of the following while on Kalydeco therapy: Improved lung function or stable lung function.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	CF (initial, reauth): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
<b>Coverage Duration</b>	CF (initial): 6 mos, (reauth): plan year
<b>Other Criteria</b>	N/A

# KISQALI

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## Products Affected

- Kisqali

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Breast cancer: Diagnosis of advanced or metastatic breast cancer. Cancer is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. Kisqali is used in combination with an aromatase inhibitor [(e.g., Femara (letrozole))].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days

# KISQALI - FEMARA PACK

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## Products Affected

- Kisqali Femara 200 Dose
- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Breast cancer: Diagnosis of advanced or metastatic breast cancer. Cancer is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days

# KORLYM

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## Products Affected

- Korlym

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	(Initial): Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus or diagnosis of glucose intolerance. Patient has either failed surgery or patient is not a candidate for surgery. Patient is not pregnant. (Reauthorization): Documentation of one of the following: patient has improved glucose tolerance while on Korlym therapy or patient has stable glucose tolerance while on Korlym therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by an endocrinologist.
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A

# LENVIMA

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## Products Affected

- Lenvima 10 Mg Daily Dose
- Lenvima 14 Mg Daily Dose
- Lenvima 18 Mg Daily Dose
- Lenvima 20 Mg Daily Dose
- Lenvima 24 Mg Daily Dose
- Lenvima 8 Mg Daily Dose

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Differentiated thyroid cancer (DTC): Diagnosis of DTC. Renal cell carcinoma: Diagnosis of Advanced Renal cell carcinoma
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# LEUPROLIDE ACETATE

## Products Affected

- Leuprolide Acetate INJ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Palliative treatment of advanced prostate cancer. Central Precocious Puberty (initial): diagnosis of central precocious puberty (idiopathic or neurogenic). Onset of secondary sexual characteristics in one of the following: females less than age 8 or males less than age 9. Confirmation of diagnosis defined by one of the following: a pubertal response to a GnRH stimulation test or bone age advanced one year beyond the chronological age. (Reauthorization): Documentation of Bone age monitoring (eg, radiographic imaging).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prostate Cancer, Central Precocious Puberty (all): plan year
Other Criteria	Prostate Cancer: Approve for continuation of prior therapy if within the past 120 days.

# LIDOCAINE PATCH

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## Products Affected

- Lidocaine PTCH

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Post-herpetic neuralgia: Diagnosis of post-herpetic neuralgia
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# LINEZOLID (IV)

## Products Affected

- Linezolid INJ 600MG/300ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	VRE infection: Invasive VRE with culture and sensitivity (C/S) report or symptomatic lower UTI by VRE w/ C/S. Nosocomial pneumonia (NP) by MRSA: NP by MRSA w/ C/S. NP by MSSA/S.pneum/MDRSP: NP by MSSA/S.pneum/MDRSP w/ C/S. Comm-acquired pneum(CAP) by MRSA: CAP by MRSA w/ C/S. CAP by MSSA: CAP by MSSA w/ C/S. CAP by S.pneum/MDRSP: CAP by S.pneum/MDRSP w/ C/S. Comp skin and skin structure infection (SSSI) by MRSA: Comp SSSI w/o osteomyelitis by MRSA w/ C/S or empirical tx of comp SSSI w/o osteomyelitis where MRSA is likely. Comp SSSI by MSSA,S.pyogenes,S.agalactiae: Comp SSSI w/o osteomyelitis by MSSA,S.pyogenes,S.agalactiae w/ C/S report. Uncomp SSSI by MRSA: Uncomp SSSI by MRSA w/ C/S or empirical tx of uncomp SSSI where MRSA is likely. Uncomp SSSI by MSSA,S.pyogenes: Uncomp SSSI by MSSA,S.pyogenes w/ C/S. Initial chronic osteomyelitis(CO) or prosthetic joint infection(PJI): Dx of CO or PJI by MRSA or MRSE w/ C/S. Reauth CO/PJI: Submission of chart documentation by ID specialist confirming prolonged tx is necessary. For all uses: Patient is unable to take oral Zyvox.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	CO, PJI: Prescribed by or in consultation with ID specialist
<b>Coverage Duration</b>	InvVRE:6wk.UTI VRE:28d.NP,CAP:21d.SSSI:14d.CO/PJI:init-6wk,reauth-6mo.



<p><b>Other Criteria</b></p>	<p>All indications: Approve for continuation of therapy upon hospital discharge. Symptomatic lower UTI (urinary tract infection) by VRE: Failure/contraindication/intolerance to 1 (or resistance to both) of following: nitrofurantoin, doxycycline. NP by MSSA/S.pneum/MDRSP: Fail/cont/intol to 2 (or resistance to all) of following: ceftriaxone, cefotaxime, levofloxacin, moxifloxacin, ampicillin-sulbactam, a carbapenem. CAP by MSSA: Fail/cont/intol to 2 (or resistance to all) of following: clindamycin, dicloxacillin, a cephalosporin. CAP by S.pneum/MDRSP: Fail/cont/intol to 2 (or resistance to all) of following: a penicillin, a macrolide, a cephalosporin, a tetracycline, a fluoroquinolone, clindamycin. Comp SSSI by MRSA: Fail/cont/intol to 1 (or resistance to all) of following: sulfamethoxazole-trimethoprim (SMZ-TMP), a tetracycline, clindamycin. Comp SSSI by MSSA,S.pyogenes,S.agalactiae: Fail/cont/intol to 2 (or resistance to all) of following:dicloxacillin, a cephalosporin, a tetracycline, amox-clav, clindamycin, sulfamethoxazole-trimethoprim (SMZ-TMP), a fluoroquinolone. Uncomp SSSI by MRSA: Fail/cont/intol to 1 (or resistance to all) of following: sulfamethoxazole-trimethoprim (SMZ-TMP), a tetracycline, clindamycin. Uncomp SSSI by MSSA,S.pyogenes: Fail/cont/intol to 2 (or resistance to all) of following: dicloxacillin, a cephalosporin, a tetracycline, amoxicillin-clavulanate, clindamycin, sulfamethoxazole-trimethoprim (SMZ-TMP), a fluoroquinolone. CO or PJI by MRSA or MRSE: Fail/cont/intol to 2 (or resistance to all) of following: sulfamethoxazole-trimethoprim (SMZ-TMP), a fluoroquinolone, a tetracycline, clindamycin.</p>
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# LINEZOLID (ORAL)

## Products Affected

- Linezolid SUSR

- Linezolid TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	VRE infection: Invasive VRE with culture and sensitivity (C/S) report or symptomatic lower UTI by VRE w/ C/S. Nosocomial pneumonia (NP) by MRSA: NP by MRSA w/ C/S. NP by MSSA/S.pneum/MDRSP: NP by MSSA/S.pneum/MDRSP w/ C/S. Comm-acquired pneum(CAP) by MRSA: CAP by MRSA w/ C/S. CAP by MSSA: CAP by MSSA w/ C/S. CAP by S.pneum/MDRSP: CAP by S.pneum/MDRSP w/ C/S. Comp skin and skin structure infection (SSSI) by MRSA: Comp SSSI w/o osteomyelitis by MRSA w/ C/S or empirical tx of comp SSSI w/o osteomyelitis where MRSA is likely. Comp SSSI by MSSA,S.pyogenes,S.agalactiae: Comp SSSI w/o osteomyelitis by MSSA,S.pyogenes,S.agalactiae w/ C/S report. Uncomp SSSI by MRSA: Uncomp SSSI by MRSA w/ C/S or empirical tx of uncomp SSSI where MRSA is likely. Uncomp SSSI by MSSA,S.pyogenes: Uncomp SSSI by MSSA,S.pyogenes w/ C/S. Initial chronic osteomyelitis(CO) or prosthetic joint infection(PJI): Dx of CO or PJI by MRSA or MRSE w/ C/S. Reauth CO/PJI: Submission of chart documentation by ID specialist confirming prolonged tx is necessary.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	CO, PJI: Prescribed by or in consultation with ID specialist
<b>Coverage Duration</b>	InvVRE:6wk.UTI VRE:28d.NP,CAP:21d.SSSI:14d.CO/PJI:init-6wk,reauth-6mo.

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**Other Criteria**

All indications: Approve for continuation upon hospital discharge. All VRE infections: Approve for continuation of therapy when transitioning from IV daptomycin or IV Zyvox therapy. Symptomatic lower UTI (urinary tract infection) by VRE (for pts not transitioning from IV): Failure/contraindication/intolerance to 1 (or resistance to both) of following: nitrofurantoin, doxycycline. All NP: Approve for continuation of therapy when transitioning from IV vancomycin or IV Zyvox therapy. NP by MSSA/S.pneum/MDRSP (for pts not transitioning from IV): Fail/cont/intol to 2 (or resistance to all) of following: ceftriaxone, cefotaxime, levofloxacin, moxifloxacin, ampicillin-sulbactam, a carbapenem. All CAP: Approve for continuation of therapy when transitioning from IV vancomycin, IV tigecycline, or IV Zyvox therapy. CAP by MSSA (for pts not transitioning from IV): Fail/cont/intol to 2 (or resistance to all) of following: clindamycin, dicloxacillin, a cephalosporin. CAP by S.pneum/MDRSP (for pts not transitioning from IV): Fail/cont/intol to 2 (or resistance to all) of following: a penicillin, a macrolide, a cephalosporin, a tetracycline, a fluoroquinolone, clindamycin. All SSSI: Approve for continuation of therapy when transitioning from IV daptomycin, IV vancomycin, IV tigecycline, IV telavancin, or IV Zyvox therapy. Comp SSSI by MRSA (for pts not transitioning from IV): Fail/cont/intol to 1 (or resistance to all) of following: sulfamethoxazole-trimethoprim (SMZ-TMP), a tetracycline, clindamycin. Comp SSSI by MSSA, S.pyogenes, S.agalactiae (for pts not transitioning from IV): Fail/cont/intol to 2 (or resistance to all) of following: dicloxacillin, a cephalosporin, a tetracycline, amox-clav, clindamycin, sulfamethoxazole-trimethoprim (SMZ-TMP), a fluoroquinolone. Uncomp SSSI by MRSA (for pts not transitioning from IV): Fail/cont/intol to 1 (or resistance to all) of following: sulfamethoxazole-trimethoprim (SMZ-TMP), a tetracycline, clindamycin. Uncomp SSSI by MSSA, S.pyogenes (for pts not transitioning from IV): Fail/cont/intol to 2 (or resistance to all) of following: dicloxacillin, a cephalosporin, a tetracycline, amoxicillin-clavulanate, clindamycin, sulfamethoxazole-trimethoprim (SMZ-TMP), a fluoroquinolone. CO, PJI: Approve for continuation of therapy when transitioning from IV daptomycin, IV vancomycin, or IV Zyvox therapy. For pts not transitioning from IV, fail/cont/intol to 2 (or resistance to all) of following: sulfamethoxazole-trimethoprim (SMZ-TMP), a fluoroquinolone, a tetracycline, clindamycin.

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# LONSURF

## Products Affected

- Lonsurf

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Metastatic colorectal cancer (mCRC): Diagnosis of mCRC. Trial and failure, contraindication, or intolerance with all of the following: fluoropyrimidine-based chemotherapy, oxaliplatin-based chemotherapy, irinotecan-based chemotherapy, and anti-VEGF biological therapy. One of the following: a) tumor is RAS mutant-type or b) tumor is RAS wild-type and Trial and failure, contraindication or intolerance to one anti-EGFR therapy (eg, Vectibix [panitumumab], Erbitux [cetuximab]).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# LUPRON DEPOT

## Products Affected

- Lupron Depot (1-month)
- Lupron Depot (3-month)
- Lupron Depot (4-month)
- Lupron Depot (6-month)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Palliative treatment of advanced prostate cancer. Endometriosis (3.75 mg, 11.25 mg) (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID and one oral contraceptive. (reauthorization): symptoms recur after one course. Used in combination with one of the following: norethindrone 5 mg daily, other "add -back" sex hormones, other bone-sparing agents. Uterine Leiomyomata (3.75 mg, 11.25 mg) (fibroids): Either for use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) Or all of the following: treatment of anemia, anemia caused by uterine leiomyomata (fibroids), and use prior to surgery.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Prostate CA: plan yr. Endometriosis(all), Uterine leiomyomata (anemia): 6 mo. (fibroids): 4 mo.
<b>Other Criteria</b>	Prostate Cancer (7.5 mg, 22.5 mg): Approve for continuation of prior therapy if within the past 120 days. Prostate Cancer (30 mg, 45 mg): Approve for continuation of prior therapy.

# LYNPARZA

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## Products Affected

- Lynparza CAPS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Ovarian cancer: Diagnosis of advanced, persistent, or recurrent ovarian cancer, presence of deleterious or suspected deleterious germline BRCA-mutations as detected by an FDA approved test, and trial and failure, contraindication or intolerance to three or more prior lines of chemotherapy (eg, paclitaxel with cisplatin).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# LYNPARZA (TABLETS)

## Products Affected

- Lynparza TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Ovarian cancer, advanced disease with known or suspected BRCA mutation with 3 or more prior lines of chemotherapy: Diagnosis of advanced, persistent, or recurrent ovarian cancer. Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by an FDA-approved test. Trial and failure, contraindication, or intolerance to three or more prior lines of chemotherapy (e.g., paclitaxel with cisplatin). Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Breast cancer: Diagnosis of breast cancer. Disease is metastatic or recurrent. Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by an FDA-approved test. Disease is human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) Disease is hormone receptor (HR) negative and patient has been previously treated with chemotherapy (e.g., anthracycline, taxane), or b) Disease is hormone receptor (HR)-positive and one of the following: i) disease has progressed on previous endocrine therapy or ii) provider attestation that treatment with endocrine therapy is inappropriate for the patient's disease.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	All indications: Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# MAVYRET

## Products Affected

- Mavyret

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
<b>Coverage Duration</b>	8 to 16 weeks (168 to 336 tabs). Criteria applied consistent with current AASLD/IDSA guideline
<b>Other Criteria</b>	N/A



# MEKINIST

## Products Affected

- Mekinist

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 AND cancer is BRAF V600 mutant type. Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type. Involvement of lymph nodes following complete resection. Used as adjuvant therapy. Medication is used in combination with Tafinlar (dabrafenib). Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type AND medication is used in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic ATC. Cancer is BRAF V600E mutant type. Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Tafinlar (dabrafenib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# MEMANTINE

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## Products Affected

- Memantine Hcl
- Memantine Hcl Titration Pak
- Memantine Hydrochloride SOLN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Age 41 or older, or diagnosis of moderate to severe dementia of the Alzheimer's type.
<b>Age Restrictions</b>	No Prior Authorization if patient is age 41 or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# METFORMIN EXTENDED RELEASE, HIGH COST

## Products Affected

- Metformin Hcl Er TB24 1000MG, 500MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>1. History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR). One of the following: a) For patients with diabetes diagnosis, documented history of an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by hemoglobin A1c level is above patient's goal OR b) documented history of intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (eg, dose reduction). AND 2. History of greater than or equal to 12 week trial of metformin immediate-release. One of the following: a) For patients with diabetes diagnosis, documented history of an inadequate response to metformin immediate-release as evidenced by hemoglobin A1c level is above patient's goal OR b) documented history of intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (eg, dose reduction).</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# MODAFINIL

## 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	<p>Obstructive sleep apnea/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work sleep disorder (SWSD) (Initial):Dx of SWSD confirmed by one of the following: 1) symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). No other medical condition or medication accounts for the symptoms. Narcolepsy (initial): Dx of narcolepsy as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). MS Fatigue (initial): Dx of multiple sclerosis (MS). Patient is experiencing fatigue. Idiopathic Hypersomnia (initial): Dx of idiopathic hypersomnia as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). Depression (initial): Treatment-resistant depression defined as diagnosis of major depressive disorder (MDD) or bipolar depression, AND trial and failure, contraindication, or intolerance to at least two antidepressants from different classes (eg, SSRIs, SNRIs, bupropion). Used as adjunctive therapy.</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A

<b>Coverage Duration</b>	Initial, Reauth: 6 mo
<b>Other Criteria</b>	OSAHS, Narcolepsy, Idiopathic Hypersomnia (Reauth): Documentation of positive clinical response to modafinil therapy. SWSD (Reauth): Documentation of positive clinical response to modafinil therapy. Patient still requires treatment for SWSD. MS Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil therapy. Depression (reauth): Documentation of positive clinical response to modafinil therapy. Used as adjunctive therapy.

# MYALEPT

## Products Affected

- Myalept

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: Diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency. Reauth: Documentation of positive clinical response to Myalept therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial: Prescribed by an endocrinologist.
<b>Coverage Duration</b>	Initial, Reauth: plan year
<b>Other Criteria</b>	Initial: One of the following: a) Diabetes mellitus or insulin resistance with persistent hyperglycemia (HgbA1C greater than 7.0%) despite optimized insulin therapy at maximum tolerated doses OR b) Persistent hypertriglyceridemia (TG greater than 250mg/dL) despite optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses.

# NATPARA

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## Products Affected

- Natpara

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Hypoparathyroidism (initial): Diagnosis of hypoparathyroidism. Unable to control hypocalcemia with standard treatments. Used as adjunctive therapy at treatment initiation. Hypoparathyroidism (reauthorization): Documentation of positive clinical response to Natpara therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial authorization: Prescribed by an endocrinologist
<b>Coverage Duration</b>	Initial: 6 months      Reauthorization: plan year
<b>Other Criteria</b>	N/A

# NERLYNX

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## Products Affected

- Nerlynx

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Breast cancer: Diagnosis (dx) of early stage breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received adjuvant trastuzumab (Herceptin) treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days



# NEULASTA

## Products Affected

- Neulasta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Neutropenia Associated with Dose Dense Chemotherapy (NDDC): Patient is receiving NCI's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, or a dose-dense regimen for which the incidence of febrile neutropenia is unknown.</p> <p>Chemotherapy-Induced Febrile Neutropenia (CFN): Patient is receiving a chemotherapy regimen associated with more than 20% incidence of febrile neutropenia, or patient is receiving chemotherapy regimen associated with 10-20% incidence of febrile neutropenia and has 1 or more risk factors associated with chemotherapy-induced infection, febrile neutropenia or neutropenia. Febrile Neutropenia (FN): For patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm<sup>3</sup>). Patient either has febrile neutropenia at high risk for infection-associated complications or has a history of febrile neutropenia during a previous course of chemotherapy.</p> <p>Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	FN (treatment), ARS: 1 mo. CFN, NDDC, FN (prophylaxis): 3 mo or duration of tx.
<b>Other Criteria</b>	N/A

# NEXAVAR

## Products Affected

- Nexavar

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renal cell carcinoma (RCC): Diagnosis of RCC and one of the following: (1) relapse following surgical excision, or (2) both of the following: medically or surgically unresectable tumor and Stage IV disease. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of one of the following: follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma. One of the following: metastatic disease, unresectable recurrent disease, or persistent locoregional disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC and one of the following: a) disease is progressive or disease is symptomatic with distant metastases. Trial and failure, contraindication, or intolerance to one of the following: Caprelsa (vandetanib) or Cometriq (cabozantinib).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	DTC, MTC: Prescribed by or in consultation with an oncologist, RCC: Prescribed by or in consultation with one of the following: oncologist or nephrologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, gastroenterologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# NINLARO

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## Products Affected

- Ninlaro

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Multiple myeloma: Diagnosis of multiple myeloma. One of the following: 1) Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)]. OR 2) Both of the following: a) Used as primary therapy and b) Used in combination with dexamethasone and Revlimid (lenalidomide)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# NORTHERA

## Products Affected

- Northera

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Neurogenic orthostatic hypotension (NOH): (Initial): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (eg, Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy. (Reauth): Documentation of positive clinical response to therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	NOH (init): Prescribed by or in consultation with one of the following specialists: cardiologist, neurologist, nephrologist.
<b>Coverage Duration</b>	Initial: 1 month. Reauth: plan year
<b>Other Criteria</b>	Trial and failure, contraindication, or intolerance to one of the following agents: Fludrocortisone acetate, midodrine.

# NOXAFIL

## Products Affected

- Noxafil TBEC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Invasive Fungal Infections (IFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy [eg, acute myeloid leukemia (AML), myelodysplastic syndrome (MDS)], OR 2) patient has a prior fungal infection requiring secondary prophylaxis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	IFI: plan year.
<b>Other Criteria</b>	N/A

# NUCALA

## Products Affected

- Nucala

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Severe eosinophilic asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by (1) peripheral blood eosinophil level measured within 6 weeks of dosing is greater than or equal to 150 cells/microliter or (2) peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months. Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months or Patient has had any prior intubation for an asthma exacerbation or Patient has had a prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with both a high dose inhaled corticosteroid (ICS) (eg, greater than 500 mcg fluticasone propionate equivalent/day) and additional asthma controller medication (eg, leukotriene receptor antagonist, long-acting beta-2 agonist [LABA], theophylline), OR one maximally-dosed combination ICS/ LABA product (eg, Advair [fluticasone propionate/ salmeterol], Dulera [mometasone/ formoterol], Symbicort [budesonide/ formoterol]), unless there is a contraindication or intolerance to these medications. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Diagnosis of EGPA. Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy). Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone).</p>
<b>Age Restrictions</b>	Severe asthma initial: Age greater than or equal to 12 years
<b>Prescriber Restrictions</b>	Severe asthma (initial, reauth): Prescribed by or in consultation with a pulmonologist or allergy/immunology specialist. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist.
<b>Coverage Duration</b>	Initial, reauth: plan year

<b>Other Criteria</b>	Severe asthma (reauth): Documentation of positive clinical response (eg, reduction in exacerbations). Patient is currently being treated with both a inhaled corticosteroid (ICS) and an additional asthma controller medication [eg, leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR a combination ICS/LABA product [eg, Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)], unless there is a contraindication or intolerance to these medications. EGPA (reauth): Documentation of positive clinical response to therapy (e.g., increase in remission time).
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# NUEDEXTA

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## Products Affected

- Nuedexta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. (Reauthorization): Documentation of clinical benefit from ongoing therapy with Nuedexta.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	PBA (initial/reauth): plan year
<b>Other Criteria</b>	N/A



# NUPLAZID

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## Products Affected

- Nuplazid TABS 17MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# ODOMZO

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## Products Affected

- Odomzo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Advanced basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma. One of the following: cancer that has recurred following surgery or radiation therapy, or patient is not a candidate for surgery or radiation therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist or oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# OFEV

## Products Affected

- Ofev

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF, defined as exclusion of other known causes of interstitial lung disease and either the presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF in patients not subjected to lung biopsy, or HRCT and surgical lung biopsy pattern revealing IPF or probable IPF in patients subjected to a lung biopsy. IPF (reauth): Documentation of positive clinical response to therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	(initial): Prescribed by a pulmonologist.
<b>Coverage Duration</b>	(initial, reauth): plan year
<b>Other Criteria</b>	(initial, reauth): Not used in combination with Esbriet.

# ONFI

## Products Affected

- Onfi SUSP

- Onfi TABS 10MG, 20MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Lennox-Gastaut syndrome: Diagnosis of Lennox-Gastaut syndrome. Used for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# ORENITRAM

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## Products Affected

- Orenitram

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH: plan year
<b>Other Criteria</b>	N/A

# ORKAMBI

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## Products Affected

- Orkambi TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cystic fibrosis (initial): Diagnosis of cystic fibrosis (CF). Submission of laboratory records confirming the patient is homozygous for the F508del mutation in the CFTR gene. (Reauthorization): Prescriber attests that the patient has achieved a clinically meaningful response while on Orkambi therapy to one of the following: lung function as demonstrated by percent predicted forced expiratory volume in 1 second (ppFEV1), body mass index (BMI), pulmonary exacerbations, quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score.
<b>Age Restrictions</b>	Patient is greater than or equal to 6 years of age
<b>Prescriber Restrictions</b>	CF (initial, reauthorization): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months. Reauth: plan year
<b>Other Criteria</b>	N/A

# OSPHENA

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## Products Affected

- Osphena

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Dyspareunia: Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Trial and failure, contraindication, or intolerance to one of the following: Estrace (estradiol) vaginal cream or Premarin (conjugated estrogens) vaginal cream.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# OXANDRIN

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## Products Affected

- Oxandrolone TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Bone Pain: Diagnosis of bone pain due to osteoporosis. AIDS Wasting: Diagnosis of AIDS wasting or cachexia associated with AIDS.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	All indications: plan year
<b>Other Criteria</b>	N/A



# PEGASYS

## Products Affected

- Pegasys

- Pegasys Proclick INJ 180MCG/0.5ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD-IDSA guidance.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	HepB: 48 wks. HepC: 20-28wks. Criteria will be applied consistent with current AASLD/IDSA guideline
<b>Other Criteria</b>	N/A

# POMALYST

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## Products Affected

- Pomalyst

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Multiple myeloma: Diagnosis of multiple myeloma. Trial and failure, contraindication or intolerance to both an immunomodulatory agent [eg, Revlimid (lenalidomide)] and a proteasome inhibitor [eg, Velcade (bortezomib)].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

## PPI, HIGH COST

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### Products Affected

- Omeprazole/sodium Bicarbonate

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Trail and failure, or intolerance to both of the following: omeprazole AND pantoprazole.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# PRALUENT

## Products Affected

- Praluent

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>Initial: One of the following diagnoses: A) HeFH as confirmed by one of the following: (1) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, AND b) One of the following: i) Family history (hx) of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii) Hx of myocardial infarction (MI) in 1st-degree relative less than 60 years of age, iii) Family hx of MI in 2nd-degree relative less than 50 years of age, iv) Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, v) Family hx of FH in 1st- or 2nd-degree relative, or (2) Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND submission of MR (e.g., chart notes, laboratory values) documenting one of the following: presence of tendinous xanthoma in pt, arcus cornealis before age 45, or functional mutation in the LDL receptor, ApoB, or PCSK9 gene. OR B) 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. One of the following: set A) Both of the following: a) One of the following LDL-C values while on max tolerated statin therapy within the last 120 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. AND b) One of the following: (1) Pt has been receiving at least 12 consecutive weeks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg] at max tolerated dose, OR (2) Both of the following: A) Pt unable to tolerate HI statin as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN)</p>
Age Restrictions	N/A
Prescriber Restrictions	Initial, reauth: Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist

<b>Coverage Duration</b>	Initial: 6 months. Reauth: plan year
<b>Other Criteria</b>	<p>Set A (continued, initial): AND B) One of the following: a) Pt has been receiving at least 12 consecutive weeks of one moderate-intensity or low-intensity statin tx and will continue to receive a MODERATE-INTENSITY or LOW-INTENSITY statin [ie, 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) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at max tolerated dose, OR b) Pt is unable to tolerate moderate-intensity or low-intensity 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 ULN), OR (3) Submission of MR documenting pt has a labeled contraindication to all statins, OR (4) Pt has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN on one statin tx. OR set B) Both of the following: a) One of the following LDL-C values while on maximally tolerated statin tx within the last 120 days: (1) LDL-C b/t 70 and 99 mg/dL with ASCVD. (2) LDL-C b/t 100 and 129 mg/dL without ASCVD. AND b) Both of the following: (1) One of the following: i) Pt has been receiving at least 12 consecutive weeks of one maximally-tolerated statin tx and will continue to receive a statin at maximally tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times ULN, iii) Submission of MR documenting patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms with statin tx with CK elevations greater than 10 times ULN on one statin tx and (2) Pt has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) tx as adjunct to maximally tolerated statin tx OR Pt has a history of contraindication or intolerance to ezetimibe. Reauth: Pt continues to receive statin at the maximally tolerated dose (unless pt has documented inability to take statins). Submission of MR (eg, lab values) documenting LDL-C reduction while on Praluent therapy. Initial, reauth: Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. All indications (initial/reauth): Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.</p>

# PRILOSEC POWDER

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## Products Affected

- Prilosec PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Trial and failure, contraindication, or intolerance to Nexium granules.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# PROMACTA

## Products Affected

- Promacta

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>Chronic idiopathic thrombocytopenic purpura (ITP): Diagnosis of chronic ITP. Chronic Hepatitis C-associated thrombocytopenia (initial): Diagnosis of chronic hepatitis C-associated thrombocytopenia. One of the following: planning to initiate and maintain interferon-based treatment or currently receiving interferon-based treatment. (Reauthorization): One of the following criteria: For patients that started treatment with Promacta prior to initiation of treatment with interferon, Promacta will be approved when both of the following are met: currently on antiviral interferon treatment for treatment of chronic hepatitis C and documentation that patient reached threshold platelet count that allows initiation of antiviral interferon therapy with Promacta treatment by week 9. OR for patients that started treatment with Promacta while on concomitant treatment with interferon, Promacta will be approved based on the following criterion: currently on antiviral interferon therapy for treatment of chronic hepatitis C. Severe Aplastic Anemia (SAA) (initial): Diagnosis of SAA. SAA (reauthorization): Documentation of positive clinical response to Promacta therapy.</p>
Age Restrictions	N/A
Prescriber Restrictions	<p>Chronic ITP and SAA: Prescribed by or in consultation with a hematologist/oncologist. Chronic hepatitis C associated thrombocytopenia: Prescribed by or in consultation with a hematologist/oncologist, gastroenterologist, hepatologist, infectious disease specialist, or HIV specialist certified through the American Academy of HIV Medicine.</p>
Coverage Duration	Hep.C thrombo(initial):3mo. SAA(initial):16wk. Chronic ITP,HepC(reauth), SAA(reauth):plan yr

<b>Other Criteria</b>	Chronic ITP: Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids, immunoglobulins, or splenectomy. SAA: Trial and failure, contraindication, or intolerance to at least one course of immunosuppressive therapy (eg, Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine).
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# PURIXAN

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## Products Affected

- Purixan

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	One of the following: History of contraindication or intolerance to generic mercaptopurine tablets OR patient is unable to swallow tablets.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by a hematologist/oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# QUININE

## Products Affected

- Quinine Sulfate CAPS 324MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Excluded if used for treatment or prevention of nocturnal leg cramps.
<b>Required Medical Information</b>	Diagnosis (dx) of uncomplicated malaria and one of the following: treatment in areas of chloroquine-sensitive malaria or treatment in areas of chloroquine-resistant malaria.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	7 days
<b>Other Criteria</b>	Chloroquine-sensitive malaria: Failure, contraindication or intolerance to chloroquine or hydroxychloroquine.

# REGRANEX

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## Products Affected

- Regranex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diabetic Neuropathic Ulcers: Patient has a lower extremity diabetic neuropathic ulcer. Treatment will be given in combination with ulcer wound care (eg, debridement, infection control, and/or pressure relief).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Diabetic Neuropathic Ulcers: 5 months.
<b>Other Criteria</b>	N/A

# RELISTOR

## Products Affected

- Relistor INJ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Opioid-induced Constipation (OIC) (advanced illness or pain caused by active cancer): Diagnosis of OIC. Patient has advanced illness, or pain caused by active cancer. OIC (non-cancer pain, pain related to prior cancer or its treatment): Diagnosis of OIC. Patient has chronic non-cancer pain, or patient has chronic pain related to prior cancer or its treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	OIC (advanced illness or pain caused by active cancer, non-cancer pain, pain related to prior cancer or its treatment): Trial and failure, contraindication, or intolerance to an osmotic laxative [eg, MiraLax/PEG3350 (polyethylene glycol (PEG)), Constulose (lactulose)]. TF/C/I to Amitiza (lubiprostone). OIC (non-cancer pain, pain related to prior cancer or its treatment): Documentation of opioid use for at least 4 weeks prior to the proposed start of therapy.

# RELISTOR TABLETS

## Products Affected

- Relistor TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Opioid-induced Constipation (OIC) (non-cancer pain, pain related to prior cancer or its treatment): Diagnosis of OIC. Patient has chronic non-cancer pain, or patient has chronic pain related to prior cancer or its treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	OIC (non-cancer, pain related to prior cancer or its treatment): Documentation of opioid use for at least 4 weeks prior to the proposed start of therapy. Trial and failure, contraindication, or intolerance (TF/C/I) to an osmotic laxative [e.g., Miralax/PEG3350 (polyethylene glycol [PEG]), Constulose (lactulose)]. TF/C/I to Amitiza (lubiprostone).

# REVLIMID

## Products Affected

- Revlimid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Multiple Myeloma: Diagnosis of multiple myeloma. Myelodysplastic syndrome (MDS) with a deletion 5q: Diagnosis of symptomatic anemia due to MDS associated with a deletion 5q. MDS without deletion 5q: Diagnosis of anemia due to MDS without deletion 5q and one of the following: A) serum erythropoietin levels greater than 500 mU/mL, OR B) Both of the following: 1) serum erythropoietin levels less than or equal to 500 mU/mL and 2) trial and failure, contraindication, or intolerance to at least one erythropoietin agent [eg, Aranesp (darboepoetin), Epogen or Procrit (epoetin alfa)]. Mantle Cell Lymphoma (MCL): Diagnosis of MCL.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# RUBRACA

## Products Affected

- Rubraca

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Ovarian cancer: Diagnosis of ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) Both of the following: a) Presence of deleterious BRCA mutation as detected by an FDA-approved diagnostic test (e.g., FoundationFocus CDxBRCA Assay) and b) Trial and failure, contraindication, or intolerance to two or more chemotherapies (e.g., cisplatin, carboplatin), OR 2) Both of the following: a) Disease is recurrent and b) Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days

# RYDAPT

## Products Affected

- Rydapt

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML), AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive, Rydapt will be used in combination with standard induction and consolidation therapy. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	All indications: Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days



# SAMSCA

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## Products Affected

- Samsca

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of significant hyponatremia (euvolemic or hypervolemic). Treatment has been initiated or re-initiated in a hospital setting prior to discharge within the past 30 days.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Length of authorization: 30 days
<b>Other Criteria</b>	N/A

# SANDOSTATIN

## Products Affected

- Octreotide Acetate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Acromegaly (initial): Diagnosis of acromegaly confirmed by one of the following: serum GH level greater than 1 ng/mL after a 2-hour oral glucose tolerance test at the time of diagnosis, or elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at the time of diagnosis. Inadequate response to surgery, radiotherapy, or dopamine agonist (eg, bromocriptine, cabergoline) therapy, or not a candidate for surgery. HIV/AIDS-Related Diarrhea (initial): Diagnosis of HIV/AIDS-related diarrhea. Carcinoid tumors, symptomatic treatment of diarrhea or flushing (initial): diagnosis of metastatic carcinoid tumor, for symptomatic treatment of severe diarrhea or flushing. Vasoactive Intestinal Peptide Tumors, symptomatic treatment of diarrhea (initial): Diagnosis of metastatic vasoactive intestinal peptide tumor, for symptomatic treatment of diarrhea associated with vasoactive intestinal peptide tumor. Cancer Chemotherapy- and/or Radiation- Induced Diarrhea (initial): Diagnosis of complicated diarrhea due to concurrent cancer chemotherapy and/or radiation or uncomplicated diarrhea due to concurrent cancer chemotherapy and/or radiation. Carcinoid tumor: diagnosis of carcinoid tumor. Reauthorization (all except carcinoid tumor): Documentation of positive clinical response to therapy.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Carcinoid tumor: 6 mo. Acromegaly (initial): 6 mo, (Reauth): plan yr. Other uses (all): 6 mo.

<b>Other Criteria</b>	Uncomplicated diarrhea due to concurrent cancer chemotherapy and/or radiation (initial): Trial and failure, contraindication, or intolerance (TF/C/I) to standard therapy (e.g., loperamide). HIV/AIDS-related Diarrhea (initial): TF/C/I to standard therapy (eg, loperamide, diphenoxylate with atropine). Carcinoid tumor: Approve for continuation of prior therapy if within the past 120 days.
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# SHINGRIX

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## Products Affected

- Shingrix

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Vaccine is being used for prevention of herpes zoster (shingles).
<b>Age Restrictions</b>	Approve for age 50 and older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months (2 injections per lifetime)
<b>Other Criteria</b>	N/A

# SIGNIFOR

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## Products Affected

- Signifor

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cushing's disease: Diagnosis of endogenous Cushing's disease (i.e, hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Either pituitary surgery has not been curative for the patient OR patient is not a candidate for pituitary surgery.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# SILDENAFIL

## Products Affected

- Sildenafil TABS 20MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH: plan year
<b>Other Criteria</b>	N/A

# SIRTURO

## Products Affected

- Sirturo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of pulmonary multidrug resistant tuberculosis (MDR-TB), adverse reactions or resistance to standard drugs used to treat MDR-TB, and one of the following: Sirturo is being used in combination with at least 3 other medications to which the patient's MDR-TB isolate has been shown to be susceptible in vitro, or if in vitro testing results are unavailable Sirturo is being used in combination with at least 4 other medications to which the patient's MDR-TB isolate is likely to be susceptible.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	24 weeks
<b>Other Criteria</b>	N/A

# SOMAVERT

## Products Affected

- Somavert

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acromegaly (Initial): Diagnosis of acromegaly by one of the following: serum growth hormone (GH) level greater than 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis, or elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis. Inadequate response to one of the following: surgery, radiotherapy, or dopamine agonist (eg, bromocriptine, cabergoline) therapy or not a candidate for surgery, or dopamine agonist (eg, bromocriptine, cabergoline) therapy. Trial and failure, contraindication, or intolerance to one of the following somatostatin analogs: Sandostatin (octreotide) or Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide) , or Patient has extremely high IGF-1 values defined as greater than 900 ng/mL. Acromegaly (Reauth): Documentation of positive clinical response to Somavert therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Acromegaly (Initial): 12 weeks. Reauth: plan year
<b>Other Criteria</b>	N/A



# SPORANOX (SOLUTION)

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## Products Affected

- Sporanox SOLN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Fungal Infections: Diagnosis of oropharyngeal or esophageal candidiasis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# SPRYCEL

## Products Affected

- Sprycel

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic Myelogenous/Myeloid Leukemia (CML): Diagnosis (dx) of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia (Ph+ CML). Acute Lymphoblastic Leukemia (ALL): Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

## STALEVO (BRAND)

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### Products Affected

- Stalevo 100
- Stalevo 125
- Stalevo 150
- Stalevo 200
- Stalevo 50
- Stalevo 75

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Trial and failure or intolerance to generic carbidopa/ levodopa/ entacapone tablets.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# STIVARGA

## Products Affected

- Stivarga

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Metastatic Colorectal Cancer (mCRC): Diagnosis of advanced or metastatic colorectal cancer. One of the following: a) Trial and failure, contraindication, or intolerance to FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan)], OR b) Trial and failure, contraindication, or intolerance to oxaliplatin-based chemotherapy and irinotecan-based chemotherapy, OR c) disease that has progressed through all available regimens. Gastrointestinal stromal tumor (GIST): Diagnosis of progressive, locally advanced, unresectable or metastatic GIST. Trial and failure, contraindication, or intolerance to imatinib mesylate or Sutent (sunitinib malate). Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Trial and failure or intolerance to Nexavar (sorafenib tosylate).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	mCRC, GIST: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# SUTENT

## Products Affected

- Sutent

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Trial and failure, contraindication, or intolerance to imatinib. Renal Cell Carcinoma (RCC): Diagnosis of RCC and one of the following: (1) Disease has relapsed, or (2) both of the following: medically or surgically unresectable tumor and diagnosis of Stage IV disease, or (3) both of the following: used in adjuvant setting and patient has a high risk of recurrence following nephrectomy. Islet Cell Tumors/Pancreatic Neuroendocrine Tumors (pNET): Diagnosis of islet cell tumors/progressive pNET.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	pNET: Prescribed by or in consultation with an oncologist or neuro-oncologist. GIST, RCC: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# SYLATRON

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## Products Affected

- Sylatron

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Melanoma: For the adjuvant treatment of melanoma with microscopic or gross nodal involvement. Administered within 84 days of surgical resection including complete lymphadenectomy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# SYMLIN

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## Products Affected

- Symlinpen 120
- Symlinpen 60

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diabetes Mellitus (DM): Type 1 or type 2 diabetes. Concurrent use of insulin therapy.
<b>Age Restrictions</b>	DM: 18 years and older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# SYNRIBO

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## Products Affected

- Synribo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic myeloid leukemia (CML): Diagnosis of chronic phase CML or accelerated phase CML or post-transplant relapse CML chronic myeloid leukemia (CML). Trial and failure, contraindication, or intolerance to two prior tyrosine kinase inhibitor therapies [eg, imatinib, Sprycel (dasatinib), Tasigna (nilotinib), Bosulif (bosutinib)].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.



# TABLOID

## Products Affected

- Tabloid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of acute myeloid leukemia
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# TAFINLAR

## Products Affected

- Tafinlar

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma AND cancer is BRAFV600 mutant type. Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type. Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Mekinist (trametinib). Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic anaplastic thyroid cancer. Cancer is BRAF V600E mutant type. Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Mekinist (trametinib).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# TAGRISSEO

## Products Affected

- Tagrisso

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is recurrent or metastatic. One of the following: 1) Used as first-line therapy AND One of the following: a) Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions, or b) Tumors are positive for EGFR exon 21 L858R mutations, or c) Disease is sensitizing EGFR mutation positive, OR 2) Disease is sensitizing EGFR mutation positive AND subsequent therapy for disease that has progressed while on Tagrisso therapy, OR 3) Tumors are positive for EGFR T790M mutation AND Trial and failure, contraindication, or intolerance to at least one prior EGFR tyrosine kinase inhibitor (TKI) therapy [e.g., Iressa (gefitinib), Tarceva (erlotinib), Gilotrif (afatinib)].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# TARCEVA

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## Products Affected

- Tarceva

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-Small Cell Lung Cancer (NSCLC): 1) Diagnosis of NSCLC. Disease is metastatic or recurrent. Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletion mutations or exon 21 (L858R) substitution mutations or a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation). Pancreatic cancer: Diagnosis of locally advanced, unresectable or metastatic pancreatic cancer. Used in combination with Gemzar (gemcitabine).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# TASIGNA

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## Products Affected

- Tasigna

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic Myelogenous/Myeloid Leukemia (CML): Diagnosis of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia (Ph+ CML).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# TAZORAC

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## Products Affected

- Tazarotene CREA
- Tazorac CREA 0.05%

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	All indications: Excluded if treatment for cosmetic purposes.
<b>Required Medical Information</b>	Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne). Psoriasis: Diagnosis of psoriasis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# TETRABENAZINE

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## Products Affected

- Tetrabenazine

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Huntington's Disease: Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia and Tourette's syndrome: Patient has stereotypes associated with tardive dyskinesia or patient has tics associated with Tourette's syndrome.
<b>Age Restrictions</b>	Tardive dyskinesia: Age greater than or equal to 18 years.
<b>Prescriber Restrictions</b>	Huntington: Prescribed by a neurologist. Tardive dyskinesia, Tourette: Prescribed by neurologist or psychiatrist.
<b>Coverage Duration</b>	Plan year.
<b>Other Criteria</b>	Tics associated with Tourette's syndrome: Trial and failure, contraindication, or intolerance to Haldol (haloperidol).

# THALOMID

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## Products Affected

- Thalomid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Erythema Nodosum Leprosum (ENL): Diagnosis (Dx) of moderate to severe ENL. One of the following: used for acute treatment OR used as maintenance therapy for prevention & suppression of cutaneous manifestations of ENL recurrence. Multiple Myeloma (MM): Dx of multiple myeloma.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	MM: Prescribed by or in consultation with an oncologist/ hematologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.



# TOBI PODHALER

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## Products Affected

- Tobi Podhaler

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# TOPICAL RETINOIDS

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## Products Affected

- Tretinoin CREA
- Tretinoin GEL 0.01%, 0.025%

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	All indications: Excluded if treatment for cosmetic purposes.
<b>Required Medical Information</b>	Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# TRACLEER

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## Products Affected

- Tracleer

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist
<b>Coverage Duration</b>	PAH: Plan year
<b>Other Criteria</b>	N/A

# TRELSTAR

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## Products Affected

- Trelstar Mixject

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prostate Cancer: Palliative treatment of advanced prostate cancer.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Prostate Cancer: Trial and failure, contraindication, or intolerance to Lupron Depot (7.5 mg, 22.5 mg, 30 mg, or 45 mg). 22.5 mg: Approve for continuation of prior therapy. All other strengths: Approve for continuation of prior therapy if within the past 120 days.

# TRIENTINE

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## Products Affected

- Trientine Hydrochloride

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration). Trial and failure, contraindication, or intolerance to Depen (penicillamine).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A

# TYKERB

## Products Affected

- Tykerb

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Breast Cancer: One of the following: A) Diagnosis of recurrent or stage IV estrogen receptor positive (ER+), human epidermal growth factor receptor 2-positive (HER2+) breast cancer. a) Patient is postmenopausal or b) patient is receiving testicular steroidogenesis suppression. Used in combination with an aromatase inhibitor [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]. OR B) Diagnosis of recurrent or metastatic HER2+ breast cancer. Patient has been previously treated with Herceptin (trastuzumab). Used in combination with Herceptin (trastuzumab) or Xeloda (capecitabine).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# TYMLOS

## Products Affected

- Tymlos

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Diagnosis of postmenopausal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) one of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: a) major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones (e.g., Forteo [teriparatide], Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year (up to 24 months per lifetime)
<b>Other Criteria</b>	N/A

# VALCHLOR

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## Products Affected

- Valchlor

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Mycosis fungoides (MF)/Sezary Syndrome (SS): Diagnosis of MF or SS. Disease is not stage IVA1, IVA2 or IVB.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.



# VANDETANIB

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## Products Affected

- Caprelsa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Thyroid Cancer: Diagnosis of unresectable locally advanced or metastatic medullary thyroid cancer
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# VENCLEXTA

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## Products Affected

- Venclexta

- Venclexta Starting Pack

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL. Patient has received at least one prior therapy for CLL/SLL [e.g., Cytosan (cyclophosphamide), Fludara (fludarabine), Rituxan (rituximab)].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# VENTAVIS

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## Products Affected

- Ventavis

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist.
<b>Coverage Duration</b>	PAH: plan year
<b>Other Criteria</b>	Subject to Part B vs D review.

# VERZENIO

## Products Affected

- Verzenio

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Breast Cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane), OR b) used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy, OR c) used as monotherapy and disease has progressed following endocrine therapy and patient has already received at least one prior chemotherapy regimen.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# VIGABATRIN

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## Products Affected

- Sabril TABS

- Vigabatrin

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Complex Partial Seizures (CPS): For use as adjunctive therapy. Infantile Spasms (IS): Diagnosis of infantile spasms.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days. CPS: Trial and failure, contraindication, or intolerance (TF/C/I) to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)].

# VOSEVI

## Products Affected

- Vosevi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and patient is not receiving Vosevi in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier]. For GT 1a patients who failed a Sovaldi-based regimen WITHOUT an NS5A inhibitor: trial and failure, contraindication, or intolerance to Mavyret OR for continuation of prior Vosevi therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.
<b>Coverage Duration</b>	12 weeks (84 tabs). Criteria will be applied consistent with current AASLD/IDSA guideline.
<b>Other Criteria</b>	N/A

# VOTRIENT

## Products Affected

- Votrient

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renal Cell Carcinoma (RCC): Diagnosis of RCC. Soft tissue sarcoma (STS): Diagnosis of advanced STS.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# XALKORI

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## Products Affected

- Xalkori

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-small Cell Lung Cancer (NSCLC): Diagnosis of metastatic or recurrent NSCLC
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.



# XATMEP

## Products Affected

- Xatmep

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acute lymphoblastic leukemia (ALL): Diagnosis of acute lymphoblastic leukemia (ALL). Polyarticular juvenile idiopathic arthritis (pJIA) (initial): Diagnosis of active polyarticular juvenile idiopathic arthritis, trial and failure, contraindication, or intolerance to an adequate trial of at least one nonsteroidal anti-inflammatory drug (NSAID).
<b>Age Restrictions</b>	ALL: Patient is 18 years of age or younger. pJIA (initial): Patient is 18 years of age or younger.
<b>Prescriber Restrictions</b>	ALL: Prescribed by or in consultation with a hematologist or oncologist. pJIA (initial): Prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	ALL: plan year. pJIA (initial, reauth): plan year
<b>Other Criteria</b>	ALL: Approve for continuation of prior therapy if within the past 120 days. pJIA (reauth): Documentation of positive clinical response to Xatmep therapy

# XGEVA

## Products Affected

- Xgeva

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prevention of skeletal-related events in patients with multiple myeloma (MM) and bone metastases from solid tumors (BMST): One of the following: 1) Diagnosis of multiple myeloma OR 2) Diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Diagnosis of giant cell tumor of bone. Tumor is unresectable or surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM) (initial): Diagnosis of hypercalcemia of malignancy and Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (eg, Aredia (pamidronate), Zometa (zoledronic acid). Hypercalcemia of malignancy (reauthorization): Documentation of positive clinical response to Xgeva therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	GCTB, Hypercalcemia of malignancy (initial): Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	MM/BMST: plan year. GCTB: 6 mo. HCM (all): 2 mo.
<b>Other Criteria</b>	Giant cell tumor of bone : Approve for continuation of prior therapy if within the past 120 days.

# XIFAXAN

## Products Affected

- Xifaxan

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Traveler's Diarrhea (TD) (only 200 mg strength): Diagnosis of traveler's diarrhea. Prophylaxis of Hepatic Encephalopathy (HE) (only 550 mg strength): Used for the prophylaxis of hepatic encephalopathy recurrence. Treatment of HE: Diagnosis of HE. Used for the treatment of HE. Trial and failure, contraindication, or intolerance to lactulose. Irritable Bowel Syndrome with Diarrhea (Initial) (only 550 mg strength): Diagnosis of irritable bowel syndrome with diarrhea (IBS-D). Trial and failure, contraindication or intolerance to an antidiarrheal agent (e.g., loperamide). Reauthorization (only 550 mg strength): Patient experiences IBS-D symptom recurrence.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	TD: 14 days (one treatment course). HE (Prophylaxis, Tx): plan year. IBS-D (initial/reauth): 2 wks
<b>Other Criteria</b>	TD: Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin).

# XOLAIR

## Products Affected

- Xolair

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Asthma (Initial): Diagnosis of moderate to severe persistent uncontrolled asthma defined by one of the following: daily asthmatic symptoms, daily use of inhaled short-acting beta2-agonist, exacerbations affect/limit activity, exacerbations (requiring oral systemic corticosteroids) greater than or equal to two times a year, nighttime awakenings more than once a week, forced expiratory volume in one second or peak expiratory flow less than or equal to 80% of predicted level, or measures of asthma control indicate uncontrolled asthma (eg, Asthma Control Test [ACT] score 19 or less). Baseline (pre-Xolair treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 700 IU/mL for patients 12 years of age and older OR greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL for patients 6 years to less than 12 years of age. Positive skin test or in vitro reactivity to a perennial aeroallergen. Chronic Idiopathic Urticaria (CIU) (Initial): Diagnosis of CIU. Asthma, CIU (Reauthorization): Documentation of positive clinical response to Xolair therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Asthma (Initial): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CIU (Initial): Prescribed by or in consultation with an allergist/immunologist, or dermatologist.
<b>Coverage Duration</b>	Asthma (Initial): 6 months. CIU (Initial): 3 months. Asthma, CIU (Reauth): 6 months

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**Other Criteria**

Asthma (Initial): Documented failure (eg, emergency room visit or hospitalization for asthma exacerbation, need for oral steroid burst) of at least 3 months to regular/routine treatment with one of the following: one combination inhaled corticosteroid/long-acting beta2-agonist [eg, Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)] or combination therapy with one inhaled corticosteroid at the maximum dosage [eg, Flovent (fluticasone propionate), Pulmicort (budesonide), QVAR (beclomethasone dipropionate)] and one long-acting beta2-agonist [eg, Foradil (formoterol fumarate), Serevent (salmeterol xinafoate)]. CIU (Initial): Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to a) two H1-antihistamines [eg, Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)] OR b) both of the following taken in combination: Second generation H1-antihistamine [eg, Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)] AND one of the following: Different second generation H1-antihistamine [eg, Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)], or first generation H1-antihistamine [eg, Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)], or H2-antihistamine [eg, Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)], or Leukotriene modifier [eg, Accolate (zafirlukast), Singulair (montelukast), Zyflo (zileuton)].

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## XTANDI (PREFERRED)

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### Products Affected

- Xtandi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Metastatic castration-resistant or recurrent prostate cancer (mCRPC): Diagnosis of castration-resistant or castration-recurrent prostate cancer. Disease is metastatic.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# XYREM

## Products Affected

- Xyrem

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND Trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Reauth: plan year
<b>Other Criteria</b>	Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with Xyrem therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy.

# ZAVESCA

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## Products Affected

- Miglustat

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Gaucher disease: Diagnosis of mild to moderate Type 1 Gaucher disease. Patient is unable to receive enzyme replacement therapy due to one of the following conditions: allergy or hypersensitivity to enzyme replacement therapy, poor venous access, or unavailability of enzyme replacement therapy (e.g. Cerezyme, VPRIV).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	N/A



# ZEJULA

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## Products Affected

- Zejula

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days

# ZELBORAF

## Products Affected

- Zelboraf

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Melanoma: Diagnosis of unresectable or metastatic melanoma. Patient is positive for BRAF V600 mutation. Erdheim-Chester Disease: Diagnosis of Erdheim-Chester disease AND Disease is BRAFV600 mutant type (MT).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Melanoma: Prescribed by or in consultation with an oncologist. Erdheim-Chester Disease: Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# ZERBAXA

## Products Affected

- Zerbaxa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Complicated intra-abdominal infection (cIAI): Diagnosis of cIAI. Infection caused by <i>Enterobacter cloacae</i> , <i>Escherichia coli</i> , <i>Klebsiella oxytoca</i> , <i>Klebsiella pneumoniae</i> , <i>Proteus mirabilis</i> , <i>Pseudomonas aeruginosa</i> , <i>Bacteroides fragilis</i> , <i>Streptococcus anginosus</i> , <i>Streptococcus constellatus</i> , or <i>Streptococcus salivarius</i> documented by culture and sensitivity report. Used in combination with metronidazole. Trial and failure to one of the following or history of resistance, contraindication, or intolerance to all of the following antibiotics: carbapenem, piperacillin-tazobactam, ticarcillin-clavulanate, tigecycline, cephalosporin in combination with metronidazole, fluoroquinolone in combination with metronidazole. Complicated urinary tract infection (cUTI): Diagnosis of cUTI. Infection caused by <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Proteus mirabilis</i> , or <i>Pseudomonas aeruginosa</i> documented by culture and sensitivity report. Trial and failure to one of the following or history of resistance, contraindication, or intolerance to all of the following antibiotics: piperacillin-tazobactam, carbapenem, cephalosporin, fluoroquinolone (except moxifloxacin).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist.
<b>Coverage Duration</b>	cIAI: 14 days. cUTI: 7 days.
<b>Other Criteria</b>	cIAI, cUTI: For continuation of therapy upon hospital discharge.

# ZOLINZA

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## Products Affected

- Zolinza

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least two systemic therapies.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# ZOSTAVAX

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## Products Affected

- Zostavax

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Vaccine is used for prevention of herpes zoster (shingles). Trial and failure, contraindication, or intolerance to Shingrix (zoster vaccine recombinant, adjuvanted).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 vaccination per lifetime.
<b>Other Criteria</b>	N/A

# ZYDELIG

## Products Affected

- Zydelig

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL, disease has relapsed or is refractory. Follicular B-cell non-Hodgkin Lymphoma (FL): Diagnosis of follicular B-cell non-Hodgkin lymphoma (FL).Not used as first-line therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	All indications: Prescribed by or in consultation with an oncologist/hematologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# ZYKADIA

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## Products Affected

- Zykadia

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC), tumor is anaplastic lymphoma kinase (ALK)-positive or ROS1-positive.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

## ZYTIGA (BRAND)

### Products Affected

- Zytiga

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Metastatic Castration-Resistant Prostate Cancer (mCRPC): Diagnosis of metastatic castration-resistant or castration-recurrent prostate cancer. Used in combination with prednisone. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] or 2) Patient received a bilateral orchiectomy. Trial and failure, or intolerance to Xtandi (enzalutamide).</p> <p>Metastatic Castration-Sensitive Prostate Cancer (mCSPC): Diagnosis of metastatic high-risk castration-sensitive prostate cancer. Used in combination with prednisone. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] or 2) Patient received a bilateral orchiectomy.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	mCRPC, mCSPC: Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	mCRPC, mCSPC: Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.



## PART B VERSUS PART D

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### Products Affected

- Abelcet
- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU
- Ambisome
- Aminosyn 7%/electrolytes
- Aminosyn 8.5%/electrolytes
- Aminosyn II INJ 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; 38MEQ/L;  
400MG/100ML; 200MG/100ML;  
270MG/100ML; 500MG/100ML
- Aminosyn II 8.5%/electrolytes
- Aminosyn-hbc
- Aminosyn-pf INJ 46MEQ/L;  
698MG/100ML; 1227MG/100ML;  
527MG/100ML; 820MG/100ML;  
385MG/100ML; 312MG/100ML;  
760MG/100ML; 1200MG/100ML;  
677MG/100ML; 180MG/100ML;  
427MG/100ML; 812MG/100ML;  
495MG/100ML; 3.4MEQ/L;  
70MG/100ML; 512MG/100ML;  
180MG/100ML; 44MG/100ML;  
673MG/100ML
- Aminosyn-pf 7%
- Aminosyn-rf
- Amphotericin B INJ
- Azathioprine TABS
- Budesonide SUSP 0.25MG/2ML,  
0.5MG/2ML
- Calcitriol CAPS
- Calcitriol ORAL SOLN
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclosporine CAPS
- Cyclosporine Modified
- Dextrose 5%
- Dextrose 5%/nacl 0.9%
- Engerix-b
- Freamine Hbc 6.9%
- Furosemide INJ
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hcl TABS
- Heparin Sodium INJ 1000UNIT/ML
- Hepatamine
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML,  
30GM/100ML
- Ipratropium Bromide INHALATION  
SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nebupent
- Nephramine
- Nutrilipid
- Ondansetron Hcl ORAL SOLN
- Ondansetron Hcl TABS
- Ondansetron Odt
- Paricalcitol CAPS
- Perforomist
- Plenamine
- Potassium Chloride INJ  
10MEQ/100ML, 20MEQ/100ML,  
2MEQ/ML, 40MEQ/100ML
- Potassium Chloride/dextrose INJ 5%;  
20MEQ/L, 5%; 40MEQ/L
- Potassium Chloride/sodium Chloride  
INJ 20MEQ/L; 0.45%, 20MEQ/L;  
0.9%, 40MEQ/L; 0.9%
- Premasol
- Procalamine
- Prosol
- Pulmozyme

- Rabavert
- Rapamune SOLN
- Recombivax Hb
- Sandimmune SOLN
- Sensipar
- Sirolimus TABS
- Sodium Chloride INJ 0.9%, 3%, 5%
- Tacrolimus CAPS
- Tobramycin NEBU
- Travasol INJ 52MEQ/L;  
1760MG/100ML; 880MG/100ML;  
34MEQ/L; 1760MG/100ML;  
372MG/100ML; 406MG/100ML;  
526MG/100ML; 492MG/100ML;  
492MG/100ML; 526MG/100ML;  
356MG/100ML; 356MG/100ML;  
390MG/100ML; 34MG/100ML;  
152MG/100ML
- 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
- Zortress

## Details

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

Plans are insured through UnitedHealthcare Insurance Company or one of its affiliated companies, a Medicare Advantage organization with a Medicare contract and a Medicare-approved Part D sponsor. Enrollment in the plan depends on the plan's contract renewal with Medicare.

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