Saver

Drugs That Require Prior Authorization (PA) Before Being Approved for Coverage

You will need authorization from **Express Scripts Medicare®** (PDP) before filling prescriptions for the drugs shown in the following chart. Express Scripts Medicare will only provide coverage after it determines that the drug is being prescribed according to the criteria specified in the chart.

You, your appointed representative or your prescriber can request prior authorization by calling Express Scripts Medicare toll free at **1.844.374.7377,** 24 hours a day, 7 days a week. Customer Service is available in English and other languages. TTY users should call **1.800.716.3231.**

The formulary may change at any time. You will receive notice when necessary.

Express Scripts Medicare (PDP) is a prescription drug plan with a Medicare contract.
Enrollment in Express Scripts Medicare depends on contract renewal.

ACYCLOVIR (TOPICAL)

Products Affected

- acyclovir topical

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Medication history
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	N/A

ADEMPAS

Products Affected

- Adempas

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PAH and CTEPH- must be precribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	3 years
Other Criteria	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Right heart cathererization is not required in pts who are currently receiving Adempas or another agent indicated for WHO group 1.

AFINITOR

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Afinitor for a Covered Use. Advanced, unresectable or metastatic neuroendocrine tumors. Perivascular Epitheloid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangioleiomyomatosis, relapsed or refractory classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Osteosarcoma, Thymomas and Thymic carcinomas, Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma.
Exclusion Criteria	N/A
Required Medical Information	HER2 status. Advanced HER2-negative breast cancer, hormone receptor (HR) status.
Age Restrictions	Relapsed or refractory classical Hodgkin lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Advanced HER2-negative breast cancer, approve if the patient is postmenopausal and has HR+ [that is, estrogen receptor positive (ER+) or progesterone positive (PR+)]disease and Afinitor will be used in combination with exemestane or tamoxifen and the patient has tried letrozole or anastrozole. Renal cell carcinoma (RCC), approve if patient meets one of the following: 1) patient has advanced RCC with predominant clear cell histology AND the patient has tried Inlyta, Votrient, Sutent, or Nexavar OR 2) patient has relapsed or medically unresectable RCC with non-clear cell histology.Tuberous sclerosis complex (TSC) for the treatment of subependymal giant cell astrocytoma (SEGA), approve if the patient requires therapeutic intervention but cannot be curatively resected. NET-approve. Osteosarcoma, approve if the patient has tried standard chemotherapy for osteosarcoma AND the patient has relapsed/refractory or has metastatic disease. Thymomas and Thymic Carcinomas, approve if the patient has tried chemotherapy. Renal angiomyolipoma with TSC-approve.

PA Criteria	Criteria Details
	WM/LPL - approve if 1. patient has progressive or relapsed disease OR 2. patient has not responded to primary therapy (e.g., Velcade+/- Rituxan, Velcade with dexamethasone +/-Rituxan, Kyprolis with Rituxan and dexamethasone, cyclophosp/doxorubicin/vincristine/pred/Rituxan, Imbruvica, Rituxan, Rituxan with cyclophosphamide and dexamethasone, Thalomid+/- Rituxan. Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma-approve if the patient's differentiated thyroid carcinoma is refractory to radioactive iodine therapy.

ALECENSA

Products Affected

- Alecensa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	metastatic NSCLC - is anaplastic lymphoma kinase (ALK)-positive

ALUNBRIG

Products Affected

- Alunbrig oral tablet 180 mg, 30 mg, 90 mg
- Alunbrig oral tablets,dose pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on brigatinib for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	ALK status, treatment history and results
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Metastatic NSCLC, patient new to therapy must be ALK-positive AND experienced progression or intolerance while on Xalkori, Zykadia or Alecensa.

AMPYRA

Products Affected

- Ampyra

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patient already started on dalfampridine extended-release for Multiple Sclerosis (MS).
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	MS. If prescribed by, or in consultation with, a neurologist or MS specialist.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

ANABOLIC STEROIDS

Products Affected

- Anadrol-50
- oxandrolone

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Girls w/Turner's Syndrome or Ullrich-Turner Syndrome (oxandrolone only), management of protein catabolism w/burns or burn injury (oxandrolone only), AIDS wasting and cachexia.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	N/A

ARCALYST

Products Affected

- Arcalyst

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent biologic therapy
Required Medical Information	N/A
Age Restrictions	Initial tx CAPS-Greater than or equal to 12 years of age.
Prescriber Restrictions	Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist.
Coverage Duration	3 mos initial, 3 years cont
Other Criteria	CAPS renewal - approve if the patient has had a response as determined by the prescriber.

ATYPICAL ANTIPSYCHOTICS

Products Affected

- aripiprazole oral solution
- aripiprazole oral tablet 10 mg, 15 mg, 2 mg, 20 mg, 30 mg, 5 mg
- aripiprazole oral tablet,disintegrating 10 mg, 15 mg
- Fanapt oral tablet 1 mg, 10 mg, 12 mg, 2 mg, 4 mg, 6 mg, 8 mg
- Fanapt oral tablets,dose pack
- Latuda oral tablet 120 mg, 20 mg, 40 mg, 60 mg, 80 mg
- olanzapine oral tablet 10 mg, 15 mg, 2.5 mg, 20 mg, 5 mg, 7.5 mg
- olanzapine oral tablet,disintegrating 10 mg, 15 mg, 20 mg, 5 mg
- paliperidone oral tablet extended release 24hr 1.5 mg, 3 mg, 6 mg, 9 mg
- quetiapine oral tablet 100 mg, 200 mg, 25 mg, 300 mg, 400 mg, 50 mg
- quetiapine oral tablet extended release 24 hr 150 mg, 200 mg, 300 mg, 400 mg, 50 mg
- Rexulti oral tablet 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg
- risperidone oral tablet 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg
- risperidone oral tablet,disintegrating 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg
- Saphris (black cherry) sublingual tablet 10 mg, 2.5 mg, 5 mg
- Vraylar oral capsule 1.5 mg, 3 mg, 4.5 mg, 6 mg
- Vraylar oral capsule,dose pack
- ziprasidone HCl oral capsule 20 mg, 40 mg, 60 mg, 80 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. Plus patients currently taking the requested drug.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For the treatment of dementia-related psychosis, may approve aripiprazole, ziprasidone, risperidone, quetiapine, or olanzapaine if the physician confirms he/she is aware of the black box warning for this indication and has assessed the risk versus benefit.

BOSULIF

Products Affected

- Bosulif oral tablet 100 mg, 400 mg, 500 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients with Phildelphia chromosome positive Acute Lymphoblastic Leukemia. Plus patients already started on Bosulif for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Bosulif is being used. For chronic myelogenous leukemia (CML), the Philadelphia chromosome (Ph) status of the leukemia must be reported. For CML, prior therapies tried must be reported to confirm resistance or intolerance.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For CML, patient must have Ph-positive CML. For ALL, patient must have Ph-positive ALL and has tried ONE other tyrosine kinase inhibitors that are used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).

BOTOX

Products Affected

- Botox

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus Achalasia. Anal Fissure. BPH. Chronic facial pain/pain associated with TMJ dysfunction. Chronic low back pain. Headache (chronic tension HA, whiplash, chronic daily HA). Palmar hyperhidrosis. Myofascial pain. Salivary hypersecretion. Spasticity (eg, due to cerebral palsy, stroke, brain injury, spinal cord injury, MS, hemifacial spasm). Essential tremor. Dystonia other than cervical (eg, focal dystonias, tardive dystonia, anismus). Frey's syndrome (gustatory sweating). Ophthalmic disorders (eg, esotropia, exotropia, nystagmus, facial nerve paresis). Speech/voice disorders (eg, dysphonias). Tourette's syndrome.
Exclusion Criteria	Use in the management of cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platsymal bands, rejuvenation of the peri-orbital region), allergic rhinitis, gait freezing in Parkinsons disease, vaginismus, interstitial cystitis, trigeminal neuralgia, or Crocodile tears syndrome.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Headache and chronic migraine - if prescribed by, or after consultation with, a neurologist or HA specialist.
Coverage Duration	Authorization will be for 12 months
Other Criteria	BPH after trial with at least 2 other therapies (eg, alpha1-blocker, 5 alpha-reductase inhibitor, TURP, transurethral microwave heat treatment, TUNA, interstitial laser therapy, stents, various forms of surgery). Chronic low back pain after trial with at least 2 other pharmacologic therapies (eg, NSAID, antispasmodics, muscle relaxants, opioids, antidepressants) and if being used as part of a multimodal therapeutic pain management program. Headache (eg,chronic tension headache, whiplash, chronic daily headache) after a trial with at least 2 other pharmacologic therapies (eg, anticonvulsants, antidepressants, beta-blockers, calcium channel blockers, non-steroidal anti-inflammatory drugs). Essential tremor after a trial with at least 1 other pharmacologic therapy (eg, primidone, propranolol,

PA Criteria	Criteria Details
	benzodiazepines, gabapentin, topiramate). Tourette's syndrome if after a trial with at least 1 more commonly used pharmacologic therapy (eg, neuroleptics, clonidine, SSRIs, psychostimulants). Chronic migraine-must have 15 or more migraine headache days per month with headache lasting 4 hours per day or longer AND have tried at least two other prophylactic pharmacologic therapies, each from a different pharmacologic class (eg, beta-blocker, anticonvulsant, tricyclic antidepressant). OAB and urinary incontinence associated with a neurological condition (eg, spinal cord injury, multiple sclerosis), approve after a trial with at least one other pharmacologic therapy (eg, anticholinergic medication).

C1 ESTERASE INHIBITORS

Products Affected

- Cinryze

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on the prescribed drug for a covered use.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders
Coverage Duration	3 years
Other Criteria	N/A

CABOMETYX

Products Affected

- Cabometyx

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with Non-Small Cell Lung Cancer with RET Gene Rearrangements. Plus patients already taking Cabometyx for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, histology, RET gene rearrangement status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Advance Renal Cell Carcinoma (Predominant Clear Cell or Non-Clear Cell Histology) - Approve

CALQUENCE

Products Affected

- Calquence

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Previous medications/therapies tried
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Mantle cell lymphoma - approve if the patient has tried one other therapy

CAPRELSA

Products Affected

- Caprelsa oral tablet 100 mg, 300 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Plus Non-Small Cell Lung Cancer with RET Gene Rearrangements
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	MTC - approve. DTC - approve if refractory to radioactive iodine therapy.

CHEMET

Products Affected

- Chemet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Blood lead level
Age Restrictions	Approve in patients between the age of 12 months and 18 years
Prescriber Restrictions	Prescribed by or in consultation with a professional experienced in the use of chelation therapy (eg, a medical toxicologist or a poison control center specialist)
Coverage Duration	Approve for 2 months
Other Criteria	Approve if Chemet is being used to treat acute lead poisoning (not as prophylaxis) and prior to starting Chemet therapy the patient's blood lead level was greater than 45 mcg/dL.

CHENODAL

Products Affected

- Chenodal

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For the treatment of gallstones, approve if the patient has tried or is currently using an ursodiol product.

CHOLBAM

Products Affected

- Cholbam oral capsule 250 mg, 50 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Combination Therapy with Chenodal
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with hepatologist, metabolic specialist, or GI
Coverage Duration	3 mos initial, 12 mos cont
Other Criteria	Bile acid synthesis d/o due to SEDs initial - Diagnosis based on an abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis. Cont - responded to initial Cholbam tx with an improvement in LFTs AND does not have complete biliary obstruction. Bile-Acid Synthesis Disorders Due to Peroxisomal Disorders (PDs), Including Zellweger Spectrum Disorders initial - PD with an abnormal urinary bile acid analysis by FAB-MS AND has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g., rickets). Cont - responded to initial Cholbam therapy as per the prescribing physician (e.g., improvements in liver enzymes, improVement in steatorrhea) AND does not have complete biliary obstruction.

CHORIONIC GONADOTROPINS (HCG)

Products Affected

- chorionic gonadotropin, human

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	N/A

COMETRIQ

Products Affected

- Cometriq

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma and patients already started on Cometriq for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy.

COPAXONE

Products Affected

- Copaxone subcutaneous syringe 40 mg/mL
- glatiramer subcutaneous syringe 20 mg/mL
- Glatopa subcutaneous syringe 20 mg/mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple scelorosis
Required Medical Information	Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

CORLANOR

Products Affected

- Corlanor

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Previous use of a Beta-blocker, LVEF, sinus rhythm, and resting HR
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	HF in pts not currently receiving Corlanor - must all of the following 1. have LVEF of less than or equal 35 percent, 2. have sinus rhythm and a resting HR of greater than or equal to 70 BPM, AND 3. tried or is currently receiving a Beta-blocker for HF (e.g., metoprolol succinate sustained-release, carvedilol, bisoprolol, carvedilol ER) unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia). HF in pts currently receiving Corlanor - had a LVEF of less than or equal to 35 percent prior to initiation of Corlanor therapy AND has tried or is currently receiving a Beta-blocker for HF unless the patient has a contraindication to the use of beta blocker therapy.

COTELLIC

Products Affected

- Cotellic

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Melanoma initial - must have BRAF V600 mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Melanoma - being prescribed in combination with Zelboraf.

CRINONE GEL

Products Affected

- Crinone vaginal gel 8 %

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, secondary amenorrhea, support of an established pregnancy.
Exclusion Criteria	Use in patients to supplement or replace progesterone in the management of infertility.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Secondary amenorrhea, 12 months.Support of an established pregnancy, 9 months.
Other Criteria	N/A

DALIRESP

Products Affected

- Daliresp

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	COPD, approve in patients who meet all of the following conditions: Patients has severe COPD or very severe COPD, AND Patient has a history of exacerbations, AND Patient has tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, indacaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone).

DARAPRIM

Products Affected

- Daraprim

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Patient's immune status
Age Restrictions	N/A
Prescriber Restrictions	Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist.
Coverage Duration	12 months
Other Criteria	Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed

DUPIXENT

Products Affected

- Dupixent

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a an allergist, immunologist or dermatologist
Coverage Duration	Initial-16 weeks, Continuation-1 year
Other Criteria	Initial Therapy- Patient meets both of the following criteria: a. Patient has used at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid for at least 28 consecutive days OR patient has atopic dermatitis affecting ONLY the face, eyes/eyelids, skin folds, and/or genitalia and has tried tacrolimus ointment for at least 28 consecutive days, AND b. Inadequate efficacy was demonstrated with these previously tried topical prescription therapies, according to the prescribing physician. Continuation- Approve if the patient has responded to Dupixent therapy as determined by the prescribing physician (e.g., marked improvements erythema, induration/papulation/edema, excoriations, and lichenification, reduced pruritus, decreased requirement for other topical or systemic therapies, reduced body surface area (BSA) affected with atopic dermatitis, or other responses observed).

EPCLUSA

Products Affected

- Epclusa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Epclusa for a Covered Use.
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin.
Required Medical Information	Genotype, prescriber specialty, other medications tried or used in combination with requested medication
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied according to AASLD guidelines. And, patients with genotype 4 must have a trial with Zepatier prior to approval of Epclusa, unless Zepatier is not specifically listed as an alternative therapy for a specific patient population in the guidelines.

EPOETIN/PROCRIT

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus anemia in patients with HIV who are receiving zidovudine. Anemic patients (Hb of 13.0 g/dL or less) at high risk for perioperative transfusions (secondary to significant, anticipated blood loss and are scheduled to undergo elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions). Plus anemia due to myelodysplastic syndrome (MDS).
Exclusion Criteria	N/A
Required Medical Information	CRF anemia in patients on and not on dialysis.Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start.Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa or Aranesp or less than or equal to 11.5 g/dL if currently receiving Mircera. Anemia w/myelosuppressive chemotx.pt must be currently receiving myelosuppressive chemo and Hb 10.0 g/dL or less to start.Hb less than or equal to 12.0 g/dL if previously on epoetin alfa or Aranesp.MDS, approve if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start.Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV (with or without zidovudine), Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 mU/mL or less at tx start.Previously on EA approve if Hb is 12.0 g/dL or less.Anemia due to ribavirin for Hep C, pt is receiving tx for HepC (e.g. RBV in combo with INF, PegINF, with or w/o direct acting antiviral agents and Hb is 10.0 g/dL or less at tx start. Previously on EA or Aranesp approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - pt is unwilling or unable to donate autologous blood prior to surgery
Age Restrictions	MDS anemia = 18 years of age and older
Prescriber Restrictions	MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.
Coverage Duration	Anemia w/myelosuppressive = 4 mos.Transfus=1 mo.Other=6mo. HIV + zidovudine = 4 mo

PA Criteria	Criteria Details
Other Criteria	N/A

ERIVEDGE

Products Affected

- Erivedge

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, patient already started on Erivedge for a covered use.
Exclusion Criteria	BCC (La or Met) - must not have had disease progression while on Odomzo.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	Locally advanced basal cell carcinoma (LABCC), approve if 1. the patient's BCC has recurred following surgery or radiation, OR 2. the patient is not a candidate for surgery and radiation therapy.

ERLEADA

Products Affected

- Erleada

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	N/A

ESBRIET

Products Affected

- Esbriet oral capsule
- Esbriet oral tablet 267 mg, 801 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Combination use with nintedanib
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	3 years
Other Criteria	IPF baseline - must have FVC greater than or equal to 50 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP.

EXJADE

Products Affected

- Exjade

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D worded as transfusion-related chronic iron overload and non-transfusion-dependent thalassemia syndromes chronic iron overload
Exclusion Criteria	N/A
Required Medical Information	Serum ferritin level
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.

FARYDAK

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	MM - must be used in combination with Velcade and dexamethasone AND previously tried Velcade and one immunomodulatory drug (i.e., Thalomid, Revlimid, or Pomalyst).

FERRIPROX

Products Affected

- Ferriprox oral tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D worded as transfusion-related due to thalassemia syndromes chronic iron overload
Exclusion Criteria	N/A
Required Medical Information	Serum ferritin level
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Initial therapy - approve if prior to starting therapy the serum ferritin level was greater than 2,500 mcg/L. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.

FIRAZYR

Products Affected

- Firazyr

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physican that specializes in the treatment of HAE or related disorders.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

FORTEO

Products Affected

- Forteo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Miacalcin, Fortical]), except calcium and Vitamin D.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 2 years
Other Criteria	Treatment of PMO, approve if pt has tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR pt has severe renal impairment (creatinine clearance less than 35 mL/min) or CKD or pt has had multiple osteoporotic fractures. Increase bone mass in men (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) with primary or hypogondal osteoporosis/Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had multiple osteoporotic fractures.

GILOTRIF

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Additional coverage is provide fro NSCLC - squamous cell carcinoma and NSCLC - HER2 positive.
Exclusion Criteria	N/A
Required Medical Information	For NSCLC - EGFR exon deletions or mutations HER2 status, or if NSCLC is squamous cell type
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	NSCLC EGFR pos - For the treatment of metastatic non small cell lung cancer (NSCLC) must be used in tumors with non-resistant EGFR mutation positive NSCLC. NSCLC squamous cell must have disease progression with first line treatment with platinum based chemotherapy. NSCLC HER2 pos - if HER2 positive NSCLC approve.

GROWTH HORMONES

Products Affected

- Norditropin FlexPro subcutaneous pen injector 10 mg/1.5 mL (6.7 mg/mL), 15 mg/1.5 mL (10 mg/mL), 5 mg/1.5 mL (3.3 mg/mL)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	GHD in children/adolescents initial must meet ONE of the following - 1. had hypophysectomy, 2. has congenital hypopituitarism AND had growth hormone response to one preferred GH test of less than 10 ng/mL (preferred tests are levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon), 3. has panhypopituitarism AND had growth hormone response to one preferred GH test of less than 10 ng/mL, has 3 or more pituitary hormone deficiencies (ACTH, TSH, LH/FSH, or prolactin), or pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior "bright spot" on MRI or CT, 4. pt had brain radiation, had growth hormone response to one preferred GH test of less than 10 ng/mL, AND meets one of these a. pretreatment growth rate (GR) is less than 7 cm/yr in children younger than 3 or b. GR is less than 4 cm/yr in 3 y/o or older, c. or if 18 y/o or younger with growth velocity that is less than 10th percentile for age/gender on last 6 months of data, OR 5. had growth hormone response to one preferred GH test of less than 10 ng/mL, ht less than the 10th percentile for age/gender, AND meets one of these a. pretreatment growth rate (GR) is less than 7 cm/yr in children younger than 3 or b. GR is less than 4 cm/yr in 3 y/o or older, c. or if 18 y/o or younger with growth velocity that is less than 10th percentile for age/gender on last 6 months of data. Continuation of tx-approve if the patient has experienced improvement, according to the prescribing physician.
Age Restrictions	ISS 5 y/o or older, SGA 2 y/o or older, SBS 18 y/o or older
Prescriber Restrictions	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.
Coverage Duration	ISS - 6 mos intial, 12 months cont tx, SBS 4 weeks, others 12 mos
Other Criteria	GHD initial in adults and adolescents 1. endocrine must certify not being

PA Criteria	Criteria Details
	prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalmic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. childhood onset has known mutations, embryonic lesions, congenital defects or irreversible structural hypothalmic pituitary lesion/damage, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L, if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, GHRH plus arginine peak of less than or equal to 11 mcg/L if BMI is less than 25, peak less than 8 mcg/L if BMI is more than 25 but less than 30, or peak less than 4 mcg/L if BMI if more than 30) AND if a transitional adolescent must be off tx for at least one month before retesting. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts older than 5 or b. growth velocity is less than 10th percentile for age/gender. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). SBS initial pt receiving specialized nutritional support. Continuation of tx-approve if the patient has experienced improvement, according to the prescribing physician.

HETLIOZ

Products Affected

- Hetlioz

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	patient is totally blind with no perception of light
Age Restrictions	18 years or older
Prescriber Restrictions	prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders
Coverage Duration	6 mos initial, 12 mos cont
Other Criteria	Initial - dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month. Cont - Approve if pt has received at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with Hetlioz under the guidance of a physician who specializes in the treatment of sleep disorders AND has achieved adequate results with Hetlioz therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep).

HIGH RISK MEDICATIONS - BENZODIAZEPINES

Products Affected

- clonazepam
- clorazepate dipotassium
- Diazepam Intensol
- diazepam oral solution 5 mg/5 mL (1 mg/mL)
- diazepam oral tablet
- lorazepam oral
- Onfi oral suspension
- Onfi oral tablet 10 mg, 20 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Procedure-related sedation = 1mo. All other conditions = 12 months.
Other Criteria	All medically accepted indications other than insomnia, authorize use. Insomnia, may approve lorazepam if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.

HIGH RISK MEDICATIONS - BENZTROPINE

Products Affected

- benztropine oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For all medically-accepted indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing benztropine for the patient and he/she would still like to initiate/continue therapy.

HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

Products Affected

- cyclobenzaprine oral tablet

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	The physician has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

Products Affected

- hydroxyzine HCl oral tablet
- promethazine oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	For promethazine, authorize use without a previous drug trial for all FDA-approved indications other than emesis, including cancer/chemo-related emesis. For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. For the treatment of non-cancer/chemo related emesis, approve promethazine hydrochloride if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant) for the current condition. Approve hydroxyzine hydrochloride if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.

HIGH RISK MEDICATIONS - PHENOBARBITAL

Products Affected

- phenobarbital

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Coverage is not provided for use in sedation/insomnia.
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For the treatment of seizures, approve only if the patient is currently taking phenobarbital.

HIGH RISK MEDICATIONS - TERTIARY TRICYCLIC ANTIDEPRESSANTS

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For the treatment of depression, approve if the patient has tried at least two of the following agents (brand or generic): citalopram, escitalopram, fluoxetine, paroxetine, sertraline, venlafaxine, desvenlafaxine, duloxetine, bupropion, mirtazapine, nortriptyline, desipramine, or trazodone. For the treatment of pain, may approve amitriptyline (single-entity only, not amitriptyline combination products) or imipramine (brand or generic) if the patient has tried at least two of the following agents: duloxetine, pregabalin, gabapentin, venlafaxine, venlafaxine Er, desipramine, or notriptyline. For the treatment of obessessive compulsive disorder (OCD), may approve clomipramine (brand or generic) if the patient has tried at least two of the following medications: fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram, or venlafaxine. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.

HIGH RISK MEDICATIONS- ESTROGENS

Products Affected

- Amabelz
- estradiol oral
- estradiol transdermal patch weekly
- Premphase

PA Criteria	Criteria Details
Covered Uses	All medically-accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Previous medication use
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	For the treatment of Vulvar Vaginal Atrophy, approve if the patient has had a trial of one of the following for vulvar vaginal atrophy (brand or generic): Estrace Vaginal Cream or estradiol valerate. For prophylaxis of Postmenopausal Osteoporosis, approve if the patient has had a trial of one of the following (brand or generic): alendronate, ibandronate, risidronate, Raloxifene, or Prolia. The physician has assessed risk versus benefit in using this High Risk medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.

HUMIRA

Products Affected

- Humira Pediatric Crohn's Start subcutaneous syringe kit 40 mg/0.8 mL, 40 mg/0.8 mL (6 pack), 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL
- Humira Pen
- Humira Pen Crohn's-UC-HS Start
- Humira Pen Psoriasis-Uveitis
- Humira subcutaneous syringe kit 10 mg/0.1 mL, 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.4 mL, 40 mg/0.8 mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D plus patients already started on adalimumab for a Covered Use.
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried
Age Restrictions	Crohn's disease (CD), 6 or older. Ulcerative colitis (UC), adults.
Prescriber Restrictions	RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist.UV-ophthalmologist
Coverage Duration	initial 3 mo, cont tx 3 years.
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. PP initial, approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as

PA Criteria	Criteria Details
	determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other agent for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) for 2 months or was intolerant to one of these agents, or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. FDA approve indications cont tx - must respond to tx as determined by prescriber. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Clinical criteria incorporated into the Humira 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling.

IBRANCE

Products Affected

- Ibrance

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus liposarcoma.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer - approve advanced (metastatic) hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Ibrance will be used as first line therapy in combination with anastrozole, exemestane, or letrozole 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with LHRH agonists, surgical bilateral oophorectomy, or ovarian irradiation AND it will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole, 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving LHRH agonist AND Ibrance with be used as first line endocrine therapy in combination with anastrozole, exemestane or letrozole, 4. Pt is postmenopausal and has relapsed or progressed during endocrine therapy (e.g. anastrozole, exemestane, letrozole, tamoxifen) AND has not previously taken Ibrance in combination with letrozole, anastrozole, or exemestane AND will be used in combination with Faslodex, 5. Pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with LHRH agonist, surgical bilateral oophorectomy, or ovarian irradiation, relapsed or progressed on prior endocrine therapy, has not previously taken Ibrance in combination with letrozole, anastrozole, or exemestane AND will be used in combination with

PA Criteria	Criteria Details
	Faslodex.

ICLUSIG

Products Affected

- Iclusig oral tablet 15 mg, 45 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Iclusig for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
Age Restrictions	CML/ALL - Adults
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	CML Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Philadelphia chromosome positive CML (e.g., Gleevec, Sprycel, Tasigna). ALL Ph+, T315I-posistive or has tried TWO other TKIs indicated for use in Ph+ ALL (e.g. Gleevec, Sprycel.)

IDHIFA

Products Affected

- Idhifa oral tablet 100 mg, 50 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Idhifa for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	IDH2-mutation status
Age Restrictions	Adults
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	AML - approve if relapsed or refractory-AND the patient is IDH2-mutation status positive as detected by an approved test

ILARIS

Products Affected

- Ilaris (PF) subcutaneous solution

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	When used in combination with concurrent biologic therapy (e.g.TNF antagonists, etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or rilonacept.
Required Medical Information	N/A
Age Restrictions	CAPS-4 years of age and older. SJIA-2 years of age and older.
Prescriber Restrictions	CAPS/MWS/FCAS initial- Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. SJIA initial- prescribed by or in consultation with a rheumatologist. FMF initial - rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, hematologist. HIDS/MKD/TRAPS initial - rheumatologist, nephrologist, geneticist, oncologist, hematologist.
Coverage Duration	CAPS/SJIA-3 mos initial, 3 years cont. FMF/HIDS/MKD/TRAPS-4 mos initial, 3 years cont.
Other Criteria	For renewal of CAPS/MWS/FCAS/SJIA/FMF/HIDS/MKD/TRAPS - After pt had been started on Ilaris, approve if the pt had a response to therapy as determined by prescribing physician. SJIA, initial therapy - approve if the pt meets one of the following: 1. has tried at least 2 other biologics for SJIA (tocilizumab, abatacet, TNF antagonists (e.g. etanercept, adalimumab, infliximab) OR 2. pt has features of poor prognosis (e.g. arthritis of the hip, radiographic damage, 6-month duration of significant active systemic disease, defined by fever, elevated inflammatory markers, or requirement for treatment with systemic glucocorticoids AND tried Actemra or Kineret OR 3. Pt has features of SJIA with active systemic features with concerns of progression to macrophage activation syndrome (MAS) [as determined by the prescribing physician] AND has tried Kineret.

IMATINIB

Products Affected

- imatinib oral tablet 100 mg, 400 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus chordoma, advanced or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. Plus patients already started on imatinib or Gleevec for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For ALL/CML, new patient must have Ph-positive for approval of imatinib.

IMBRUVICA

Products Affected

- Imbruvica oral capsule 140 mg, 70 mg
- Imbruvica oral tablet 140 mg, 280 mg, 420 mg, 560 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Imbruvica for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Marginal Zone Lymphoma - Approve if the patient has tried Rituxan (rituximab for intravenous infusion) or according to the prescribing physician, Rituxan is contraindicated for use in this patient.

INLYTA

Products Affected

- Inlyta oral tablet 1 mg, 5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Plus, patients already started on Inlyta for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Advanced renal cell carcinoma, approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy.

IRESSA

Products Affected

- Iressa

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Metastatic NSCLC - The patient has epidermal growth factor receptor (EGFR) exon 19 deletions OR has exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

IVIG

Products Affected

- Privigen

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Part B versus D determination per CMS guidance to establish if drug used for PID in pts home.

JAKAFI

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, patients already started on Jakafi for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For polycythemia vera patients must have tried hydroxyurea

KADCYLA

Products Affected

- Kadcyla

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Use as adjuvant therapy.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	3 years
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.

KALYDECO

Products Affected

- Kalydeco oral granules in packet
- Kalydeco oral tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Combination use with Orkambi
Required Medical Information	N/A
Age Restrictions	two years of age and older
Prescriber Restrictions	prescribed by or inconsultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	3 years
Other Criteria	CF - must have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, D1270N, G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, G1349D, 2789+5G A, 3272-26A G, 3849+10kbC T, 711+3A G, E831X OR R117H AND must NOT be Homozygous for the F508del Mutation in the CFTR Gene or have unknown CFTR gene mutations.

KEYTRUDA

Products Affected

- Keytruda intravenous solution

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, patients already started on pembrolizumab for a Covered Use, Classical Hodgkin Lymphoma (cHL), and Merkel cell carcinoma (MCC).
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous medication therapies (past and/or concomitant), prescriber specialty, disease status, mutation status, transplant history
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Initial approval, 6 months. Continuation, approve at 6 month intervals
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Head and Neck Squamous Cell Carcinoma (HNSCC)-approve if the patient meets BOTH of the following conditions: 1) patient has recurrent or metastatic disease, AND 2) patient has disease progression on or after trying platinum containing chemotherapy OR patient has tried chemotherapy for recurrent or metastatic disease OR platinum-containing chemotherapy or other chemotherapy regimen is contraindicated according to the prescribing physician. Melanoma-approve if the patient has unresectable, advanced, or metastatic melanoma AND pembrolizumab will not be used in combination with ipilimumab. Non-Small Cell Lung Cancer (NSCLC)-approve if the patient meets criteria ALL (1, 2 and 3) of the following conditions: 1) patient has metastatic disease, AND 2) if the patient has non-squamous cell carcinoma, testing has been completed for EGFR exon 19 deletion or exon 21 (L858R) substitution, ALK fusions or ROS1 rearrangements and the patient meets the ONE of the following conditions (a or b or c): a) if the patient's tumor has EGFR exon 19 deletion or exon 21 (L858R) substitution, prior targeted therapy with Tarceva (erlotinib), Gilotrif (afatinib), or Iressa (gefitinib) has been tried, OR b) if the patient's tumor is positive for ALK fusions, prior targeted therapy with Xalkori (crizotinib) or Zykadia (ceritinib) or Alecensa (alectinib) has been tried, OR c) if the

PA Criteria	Criteria Details
	patient's tumor is positive for ROS1 rearrangements, prior targeted therapy with Xalkori (crizotinib) has been tried, AND 3) the patient's tumor expresses programmed death-ligand 1 (PD-L1) as determined by a FDA-approved test and ONE of the following applies (a or b): a) The tumor proportion score (TPS) is greater than or equal to 50%, OR b) the tumor proportion score (TPS) is greater than or equal to 1% and the patient has tried systemic chemotherapy and the patient has not previously been treated with Keytruda, Opdivo, or Tecentriq. cHL-approve if Keytruda is being used as single agent therapy and if the patient meets ONE of the follow conditions: 1) patient has relapsed after autologous hematopoietic stem-cell transplantation, OR 2) patient has relapsed after receiving brentuximab vedotin intravenous injection, OR 3) Keytruda will be used as palliative therapy. MCC-approve if the patient has distant metastatic disease or disseminated recurrence of disease.

KISQALI

Products Affected

- Kisqali
- Kisqali Femara Co-Pack

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer - approve advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Kisqali will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with LHRH agonist, surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving LHRH agonist AND Kisqali with be used as first line endocrine therapy in combination with anastrozole, exemestane or letrozole.

LENVIMA

Products Affected

- Lenvima

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with Medullary Thyroid Carcinoma (MTC).
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	DTC - must be refractory to radioactive iodine treatment for approval. RCC - approve if the pt meets ONE of the following criteria: 1) pt has RCC with predominant clear-cell histology AND the pt has tried one antiangiogenic therapy (eg, Inlyta, Votrient, Sutent, Nexavar) AND Lenvima will be used in combination with everolimus (Afinitor), OR 2) pt has RCC with non-clear cell histology AND Lenvima will be used in combination with everolimus (Afinitor). MTC-approve if the patient has tried Caprelsa or Cometriq.

LETAIRIS/TRACLEER

Products Affected

- Letairis
- Tracleer

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Chronic thromboembolic pulmonary hypertension (CTEPH) (Tracleer).
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) WHO Group 1 patients not currently on Letairis or Tracleer or another agent indicated for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently on Letairis or Tracleer or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization.
Age Restrictions	N/A
Prescriber Restrictions	For treatment of pulmonary arterial hypertension, Letairis or Tracleer must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH - prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Authorization will be for 3 years.
Other Criteria	CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving Tracleer for CTEPH.

LEUPROLIDE (LONG ACTING)

Products Affected

- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)
- Lupron Depot-Ped (3 month) intramuscular syringe kit 30 mg
- Lupron Depot-Ped intramuscular kit 11.25 mg, 15 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D but specific to the following drugs as follows: Prostate cancer (Lupron Depot), Endometriosis (Lupron Depot), Uterine leiomyomata (Lupron Depot), Treatment of central precocious puberty (Lupron Depot Ped). Ovarian cancer (Lupron Depot, Lupron Depot Ped). Breast cancer (Lupron Depot, Lupron Depot Ped). Prophylaxis or treatment of uterine bleeding in premenopausal patient with hematologic malignancy or prior to bone marrow/stem cell transplantation (BMT/SCT) (Lupron Depot, Lupron Depot Ped). Uterine bleeding (Lupron Depot, Lupron Depot Ped).
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	For abnormal uterine bleeding/endomet/uterine leiomyomata approve up to 6 months/all other dx 12 mo
Other Criteria	N/A

LIDODERM

Products Affected

- lidocaine topical adhesive patch,medicated

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus diabetic neuropathic pain.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	N/A

LONG ACTING OPIOIDS (ORAL)

Products Affected

- buprenorphine transdermal patch weekly 10 mcg/hour, 15 mcg/hour, 20 mcg/hour, 5 mcg/hour
- Butrans transdermal patch weekly 7.5 mcg/hour
- methadone oral solution 10 mg/5 mL, 5 mg/5 mL
- methadone oral tablet 10 mg, 5 mg
- morphine oral tablet extended release 100 mg, 15 mg, 200 mg, 30 mg, 60 mg
- oxymorphone oral tablet extended release 12 hr

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D worded as pain severe enough to require daily, around-the-clock, long-term opioid treatment. Plus patients with a cancer diagnosis, patients in a hospice program/end-of-life care/palliative care
Exclusion Criteria	Acute (ie, non-chronic) pain
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer diagnosis and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), unless unavailable in the state, AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.

LONSURF

Products Affected

- Lonsurf

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Metastatic CRC - As per labeling, the patient has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-FU) AND oxaliplatin AND irinotecan AND if the tumor or metastases are wild-type KRAS and/or NRAS (that is, the tumors or metastases are KRAS and/or NRAS mutation negative) Erbitux or Vectibix has been tried.

LYNPARZA

Products Affected

- Lynparza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Lynparza.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Ovarian cancer approve if the patient has a germline BRCA mutation AND as per product labeling, has progressed on three or more prior lines of chemotherapy.

MEGACE

Products Affected

- megestrol oral suspension 400 mg/10 mL (40 mg/mL), 625 mg/5 mL
- megestrol oral tablet

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Coverage is not provided for weight gain for cosmetic reasons.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

MEKINIST

Products Affected

- Mekinist oral tablet 0.5 mg, 2 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with Non-Small Cell Lung Cancer (NSCLC) and patients already started on Mekinist for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Mekinist is being used. For unresectable or metastatic melanoma and NSCLC must have documentation of BRAF V600 mutationss
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For unresectable or metastatic melanoma must be used in patients with BRAF V600 mutation, not being used in combination with Zelboraf, and either 1. be used in combination with Tafinlar per product labeling or 2. be used as monotherapy in a patient who has not experienced disease progression on a BRAF Inhibitor for Melanoma (i.e., Tafinlar or Zelboraf). For NSCLC requires BRAF V600E Mutation and use in combination with Tafinlar.

MEMANTINE

Products Affected

- memantine oral capsule,sprinkle,ER 24hr
- memantine oral solution
- memantine oral tablet
- memantine oral tablets,dose pack
- Namenda Titration Pak
- Namenda XR
- Namzaric

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients with mild to moderate vascular dementia.
Exclusion Criteria	N/A
Required Medical Information	Indication for which memantine is being prescribed.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	N/A

MYALEPT

Products Affected

- Myalept

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or a geneticist physician specialist
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

NATPARA

Products Affected

- Natpara

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	3 years
Other Criteria	Chronic hypoparathyroidism, initial therapy - approve if before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician. Chronic hypoparathyroidism, continuing therapy - approve if during Natpara therapy, the patient's 25-hydroxyvitamin D stores are sufficient per the prescribing physician AND the patient is responding to Natapara therapy, as determined by the prescriber.

NERLYNX

Products Affected

- Nerlynx

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Stage of cancer, HER2 status, previous or current medications tried
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Approve for 12 months
Other Criteria	Breast cancer - approve if the patient meets all of the following criteria: 1. Patient has early stage disease, AND 2. Patient has HER2-positive breast cancer, AND 3. Patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy.

NEULASTA

Products Affected

- Neulasta subcutaneous syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients undergoing PBPC collection and therapy
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist. PBPC - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation. Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC/Radiation Syndrome-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years), prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, OR the patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.

NEUPOGEN

Products Affected

- Neupogen

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D worded more broadly as cancer patients receiving myelosuppressive chemotherapy, patients with acute myeloid leukemia (AML) receiving chemotherapy, cancer patients receiving bone marrow transplantation (BMT), patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy, and patients with severe chronic neutropenia [SCN] (e.g., congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL).
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	AML, HIV/AIDS, MDS - adults
Prescriber Restrictions	Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 months.MDS-3 mo.PBPC,Drug induce A/N,AA,ALL,BMT-1 mo.All others=12mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditio ns: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver or

PA Criteria	Criteria Details
	renal dysfunction, poor performance status, HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, Neulasta, Neupogen Granix, or Zarxio) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).

NEXAVAR

Products Affected

- Nexavar

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus , patients already started on Nexavar for a covered use, osteosarcoma, angiosarcoma, advanced or unresectable desmoids tumors, gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, Chordoma with recurrent disease, solitary fibrous tumor and hemangiopericytoma
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Osteosarcoma, approve if the patient has tried standard chemotherapy and have relapsed/refractory or metastatic disease. GIST, approve if the patient has tried TWO of the following: imatinib mesylate (Gleevec), sunitinib (Sutent), or regorafenib (Stivarga). Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). AML - Approve

NINLARO

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus , patients already started on Ninlaro.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	MM - be used in combination with Revlimid and dexamethasone AND pt had received at least ONE previous therapy for multiple myeloma (e.g., Velcade, Kyprolis, Thalomid, Revlimid, Pomalyst, Alkeran, dexamethasone, prednisone).

NORTHERA

Products Affected

- Northera

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Medication history
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a neurologist
Coverage Duration	12 months
Other Criteria	NOH, approve if the patient meets ALL of the following criteria: a) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinsons disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND b) Patient has tried midodrine

NUCALA

Products Affected

- Nucala

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with Xolair
Required Medical Information	N/A
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
Coverage Duration	Authorization will be for 6 months initial, 12 months continuation.
Other Criteria	Initial - must have peripheral blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks (prior to treatment with an IL-5 antagonist monoclonal antibody) AND Patient has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following A. inhaled LABA, B. inhaled long-acting muscarinic antagonist, C. Leukotriene receptor antagonist, or D. Theophylline. Patient's asthma continues to be uncontrolled as defined by ONE of the following - patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, patient has a FEV1 less than 80 percent predicted, Patient has an FEV1/FVC less than 0.80, or Patient's asthma worsens upon tapering of oral corticosteroid therapy. Continuation - The patient has responded to Nucala therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy) AND Patient continues to receive therapy with an inhaled corticosteroid.

NUEDEXTA

Products Affected

- Nuedexta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	N/A

NUVIGIL/PROVIGIL

Products Affected

- modafinil

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Excessive daytime sleepiness (EDS) due to myotonic dystrophy - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients must be greater than or equal to 17 years of age.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Excessive sleepiness due to SWSD if the patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression.

OCALIVA

Products Affected

- Ocaliva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Ocaliva for a covered use.
Exclusion Criteria	N/A
Required Medical Information	Prescriber specialty, lab values, prior medications used for diagnosis and length of trials
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial and continuation therapy)
Coverage Duration	6 months initial, 3 years cont.
Other Criteria	Intial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following:a)Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b)Positive anti-mitochondrial antibodies (AMAs) c)Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)).

ODOMZO

Products Affected

- Odomzo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus metastatic BCC.
Exclusion Criteria	N/A
Required Medical Information	BCC - Must not have had disease progression while on Erivedge (vismodegib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Locally advanced BCC approve ifthe BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metatastic BCC - approve.

OFEV

Products Affected

- Ofev

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Combination use with pirfenidone
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	3 years
Other Criteria	IPF baseline - must have FVC greater than or equal to 50 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP.

OPDIVO

Products Affected

- Opdivo intravenous solution 100 mg/10 mL, 40 mg/4 mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, patients already started on nivolumab for a Covered Use, Small Cell Lung Cancer (SCLC)[non-FDA labeled indication]
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous medication therapies (past and/or concomitant), prescriber specialty, disease status, mutation status, transplant history
Age Restrictions	cHL, 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Initial approval, 6 months. Continuation, approve at 6 month intervals
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Head and Neck Squamous Cell Carcinoma (HNSCC)-approve if the patient meets BOTH of the following conditions: 1) patient has recurrent or metastatic disease, AND 2) patient has disease progression on or after trying platinum containing chemotherapy OR patient has tried chemotherapy for recurrent or metastatic disease OR platinum-containing chemotherapy or other chemotherapy regimen is contraindicated according to the prescribing physician. Classical Hodgkin Lymphoma (cHL)-approve if Opdivo is being used as single agent therapy and if the patient meets ONE of the follow conditions: 1) patient has relapsed after autologous hematopoietic stem-cell transplantation, OR 2) patient has relapsed after receiving brentuximab vedotin intravenous injection, OR 3) Opdivo will be used as palliative therapy. Melanoma-approve if the patient has unresectable, advanced, or metastatic melanoma. Non-Small Cell Lung Cancer (NSCLC)-approve if the patient meets criteria ALL (1, 2, 3 and 4) of the following conditions: 1) patient has metastatic disease, AND 2) patient has tried systemic chemotherapy, AND 3) patient has not previously been treated with Keytruda, Opdivo, or Tecentriq, AND 4) if the patient has non-squamous cell carcinoma, testing has been completed for EGFR exon 19 deletion or exon 21 (L858R) substitution, ALK fusions or ROS1 rearrangements and

PA Criteria	Criteria Details
	the patient meets the ONE of the following conditions (a or b or c): a) if the patient's tumor has EGFR exon 19 deletion or exon 21 (L858R) substitution, prior targeted therapy with Tarceva (erlotinib), Gilotrif (afatinib), or Iressa (gefitinib) has been tried, OR b) if the patient's tumor is positive for ALK fusions, prior targeted therapy with Xalkori (crizotinib) or Zykadia (ceritinib) or Alecensa (alectinib) has been tried, OR c) if the patient's tumor is positive for ROS1 rearrangements, prior targeted therapy with Xalkori (crizotinib) has been tried. Renal Cell Carcinoma (RCC)-approve if the patient meets BOTH of the following conditions: 1) patient has advanced (ie, relapsed or Stage IV and surgically unresectable) disease, AND 2) patient has RCC with predominant clear-cell histology and has tried one of Sutent (sunitinib), Inlyta (axitinib), Votrient (pazopanib), or Nexavar (sorafenib) OR the patient has RCC with non-clear cell histology. Urothelial Carcinoma-approve if the patient has recurrent, locally advanced, or metastatic urothelial carcinoma and meets ONE of the following conditions: 1) patient has disease progression after trying platinum containing chemotherapy, OR 2) patient has tried chemotherapy, OR 3) a platinum containing chemotherapy regimen or other chemotherapy is contraindicated according to the prescribing physician. SCLC-approve if the patient has relapsed or progressed after receiving a platinum containing chemotherapy.

ORENCIA

Products Affected

- Orencia
- Orencia ClickJect

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients who have already been started on abatacept (IV or SC) for a covered use.
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	N/A
Prescriber Restrictions	RA and JIA/JRA prescribed by or in consultation with a rheumatologist.
Coverage Duration	3 mos initial, 3 years cont
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], approve if the patient meets one of the following criteria: 1) Patient has tried adalimumab. [Note: the patient does not have to have a trial with Humira if they have had a trial with Enbrel, Actemra IV or infliximab in the past.], OR 2) According to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder, or a previous serious infection. Cont tx - responded to therapy as per the prescriber.

ORKAMBI

Products Affected

- Orkambi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Combination use with Kalydeco
Required Medical Information	N/A
Age Restrictions	6 years of age and older
Prescriber Restrictions	prescribed by or inconsultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	3 years
Other Criteria	CF - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation)

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

- Adcirca
- sildenafil (Pulmonary Arterial Hypertension) oral tablet 20 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) WHO Group 1, patients not currently taking an agent indication for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1patients currently receiving an agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization.
Age Restrictions	N/A
Prescriber Restrictions	For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets and suspension (Revatio, generics) require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception.

PRALUENT

Products Affected

- Praluent Pen subcutaneous pen injector
  150 mg/mL, 75 mg/mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use of Juxtapid or Kynamro.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history
Age Restrictions	18 years of age and older.
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Hyperlipidemia in patients with HeFH without ASCVD -approve if meets all of the following 1. Pt has been diagnosed with HeFH AND 2. tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or Crestor greater than or equal to 20 mg daily) AND 3. LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. Hyperlipidemia Pt with Clinical ASCVD with or without HeFH -approve if meets all of the following has an LDL-C greater than or equal to 70 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 therapy), AND has one of the following conditions prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND tried ONE high intensity statin (as defined above) AND LDL-C remains greater than or equal to 70 mg/dL unless the pt is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c.

PROLASTIN-C

Products Affected

- Prolastin-C intravenous recon soln

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, pretreatment AAT serum concentration
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Alpha1-Antitrypsin (AAT) Deficiency with Emphysema (or COPD) - approve in patients with baseline (pretreatment) AAT serum concentration of less than 80 mg/dL (11 micromol/L).

PROLIA

Products Affected

- Prolia

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Miacalcin, Fortical]), except calcium and Vitamin D.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Treatment of postmenopausal osteoporosis/Treatment of osteoporosis in men (to increase bone mass) [a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression], approve if the patient meets one of the following: 1. has had inadequate response after 12 months of therapy with an oral bisphosphonate, had osteoporotic fracture while receiving an oral bisphosphonate, or intolerability to an oral bisphosphonate, OR 2. the patient cannot take an oral bisphosphonate because they cannot swallow or have difficulty swallowing, they cannot remain in an upright position, or they have a pre-existing GI medical condition, OR 3. pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR 4. the patient has severe renal impairment (eg, creatinine clearance less than 35 mL/min) or chronic kidney disease, or if the patient has multiple osteoporotic fractures. Treatment of bone loss in patient at high risk for fracture receiving ADT for nonmetastatic prostate cancer, approve if the patient has prostate cancer that is not metastatic to the bone and the patient is receiving ADT (eg, leuprolide, triptorelin, goserelin) or the patient has undergone a bilateral orchiectomy. Treatment of bone loss (to increase bone mass) in patients at high risk for fracture receiving adjuvant AI therapy for breast cancer, approve if the patient has breast cancer that is not metastatic to the bone and in receiving concurrent AI therapy (eg, anastrozole, letrozole, exemestane).

PROMACTA

Products Affected

- Promacta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Thrombocytopenia due to hepatitis C virus (HCV)-related cirrhosis.
Exclusion Criteria	Use in the management of thrombocytopenia in myelodysplastic syndrome (MDS).
Required Medical Information	Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Thrombocytopenia due to chronic ITP or Aplastic Anemia, approve if prescribed by, or after consultation with, a hematologist. Thrombocytopenia due to HCV-related cirrhosis, approve if prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease.
Coverage Duration	Chronic ITP - 3 years, others 12 months.
Other Criteria	Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura, approve if the patient has tried corticosteroids or IVIG or has undergone a splenectomy. Treatment of thrombocytopenia due to HCV-related cirrhosis, approve to allow for initiation of antiviral therapy if the patient has low platelet counts (eg, less than 75,000 mm3) and the patient has chronic HCV infection and is a candidate for hepatitis C therapy. Aplastic anemia - has low platelet counts at baseline/pretreatment (e.g., less than 30,000 mm3) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate moefetil, sirolimus, Atgam)

RADICAVA

Products Affected

- Radicava

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Results of El Escorial or revised Airlie House diagnostic criteria, ALSFRS-R score, FVC %, previous or current medications, time elapsed since diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.
Coverage Duration	Initial, 6 months. Continuation, 12 months
Other Criteria	ALS, initial therapy - approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, AND 2. Patient has a score of two points or more on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. Patient has a FVC greater than or equal to 80% (ie, normal respiratory function), AND 4. Patient has been diagnosed with ALS for less than or equal to 2 years. ALS, continuation therapy - approve if, according to the prescribing physician, the patient continues to benefit from therapy AND the patient is not requiring invasive ventilation.

REBIF

Products Affected

- Rebif (with albumin)
- Rebif Rebidose subcutaneous pen injector 22 mcg/0.5 mL, 44 mcg/0.5 mL, 8.8mcg/0.2mL-22 mcg/0.5mL (6)
- Rebif Titration Pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients who expereinced an attack and are at risk for multiple sclerosis.
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	Diagnosis of MS includes the following patient types: patients with actual diagnosis of MS, patients who have experienced an MS attack, and patients who are at risk for developing MS.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

RECLAST

Products Affected

- zoledronic acid-mannitol-water

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent Use with Other Medications for Osteoporosis (e.g., other bisphosphonates, Prolia, Forteo, Evista, calcitonin nasal spray), except calcium and Vitamin D.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Paget's 1 month. Others 12 months.
Other Criteria	Tx of osteoporosis in post menopausal patient or osteoporosis in men (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression), must meet ONE of the following: pt had an inadequate response after 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had an osteoporotic fracture while receiving therapy or pt experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphosphonate because pt cannot swallow or has difficulty swallowing or pt cannot remain in upright position post oral bisphos admin or pt has pre-existing GI medical condition (eg, pt with esophageal lesions/ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried IV Reclast. Tx of PMO may have also tried IV Boniva for approval. Prevention or treatment of glucocorticoid induced osteoporosis (GIO), approve if: pt is initiating or continuing therapy with systemic glucocorticoids, AND has had an inadequate response after 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had an osteoporotic fracture while on therapy or pt experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphosphonate because pt cannot swallow or has difficulty swallowing or pt cannot remain in an upright position post oral

PA Criteria	Criteria Details
	bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), or has tried Reclast. Tx of Paget's disease, approve if pt has elevations in serum alkaline phosphatase of two times higher than the upper limit of the age-specific normal reference range, OR pt is symptomatic (eg, bone pain, hearing loss, osteoarthritis), OR pt is at risk for complications from their disease (eg, immobilization, bone deformity, fractures, nerve compression syndrome). Preventions of PMO - meets one of the following had an inadequate response after a trial duration of 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or patient had an osteoporotic fracture while receiving therapy or patient experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions/ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried Reclast.

REMICADE

Products Affected

- Remicade

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D plus patients already started on infliximab (Remicade or Inflectra) for non-Crohn's disease covered uses. Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Juvenile Idiopathic Arthritis (JIA). Sarcoidosis
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medication, previous medications tried
Age Restrictions	CD and UC, Pts aged 6 years or more.
Prescriber Restrictions	Prescribed by or in consult w/:RA/AS/Still's/JIA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's- rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarcoidosis-pulmonol, ophthalmol, or dermatol.
Coverage Duration	FDA ind/JIA initial - 3 mos, cont 3 years, others 12 mo
Other Criteria	Approve for RA if pt has tried Humira. [Note: the patient does not have to have a trial with one of the drugs listed if they have had a trial with Enbrel, Cimzia or Simponi SC in the past.] Approve for Ankylosing Spondylitis and PsA if the patient has tried Humira. [Note: the patient does not have to have a trial with adalimumab if they have had a trial with Enbrel, Cimzia or Simponi SC in the past.] CD in patients aged greater than 6 years but less than 18 years, approve if the pt has tried corticosteroid (CS) or if CSs contraindicated or if currently on CS or if the patient has tried one other agent for CD (eg, azathioprine, 6-MP, MTX, certolizumab, adalimumab, Entyvio) OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had ileocolonic resection. CD in patients 18 years or more, approve if the patient has tried adalimumab. [Note: the patient does not have to try adalimumab if they have tried Cimzia in the past.] Plaque psoriasis (PP).Pt tried adalimumab or ustekinumab. (Note: a patient who has tried Enbrel does not need to have a

PA Criteria	Criteria Details
	trial one of the drugs listed.).Ulcerative colitis (UC).Tried 2-mo trial of systemic CS, 6-MP, AZA, CSA or tacrolimus or was intolerant to one of these agents OR the patient has pouchitis AND has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Behcet's.Pt has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa), Enbrel or Humira OR has ophthalmic manifestations. SD.Tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant.UV.Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab.Sarcoidosis.Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide.Pyoderma gangrenosum (PG).Tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos. Hidradenitis suppurativa (HS).Tried 1 tx (eg, intralesional/oral CS, systemic antibiotic, isotretinoin).GVHD.Tried 1 tx (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.) or receiving IFX concurrently. JIA (regardless of type of onset) approve if Remicade started in combination with MTX or one other traditional DMARD (eg, leflunomide, sulfasalazine) AND the pt has tried 1 other agent for this condition (eg, MTX, sulfasalazine, or leflunomide, an NSAID, or one biologic DMARD [eg, Humira, Orencia, Enbrel, Kineret, Actemra]) or the pt has aggressive disease. FDA approved indications cont tx - approve if patient has had a response, as determined by the prescriber.

REMODULIN

Products Affected

- Remodulin

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	PAH WHO group, right heart catherization results, WHO functional status, previous drugs tried
Age Restrictions	N/A
Prescriber Restrictions	PAH WHO Group 1, prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. PAH WHO Group 1, patients not currently on Remodulin pt required to have had a right-heart catheterization to confirm the diagnosis of PAH (mPAP greater than or equal to 25 mm Hg at rest, PCWP equal to or less than 15 mm Hg, and PVR greater than 3 Wood units) AND have Class II, III, or IV WHO functional status AND if the pt has idiopathic PAH, they must have one of the following: 1. had an acute response to vasodilator testing that occured during the right heart cath (defined as decrease in mPAPof at least 10 mm Hg to an absolute mPAP of less than 40 mm Hg without a decrease in cardiac output) AND has tried an oral CCB or 2. pt did not have an acute response to vasodilator testing or 3. cannot undergo vasodilator test or cannot take CCB due to extreme right HF (e.g. hypotension, cardiac index less than 1.5, or right atrial pressure greater than 20, or 4. has tried a CCB without vasodilator testing. PAH WHO Group1, patients currently on Remodulin- pt must have had a right heart catherization to confirm the diagnosis of PAH.

REPATHA

Products Affected

- Repatha
- Repatha Pushtronex
- Repatha SureClick

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use of Juxtapid, Kynamro, or Praluent.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history
Age Restrictions	ASCVD/HeFH/Primary Hyperlipidemia - 18 yo and older, HoFH 13 yo and older.
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
Coverage Duration	Approve for 3 years for ASCVD/HeFH/HoFH. Approve for 1 year for primary hyperlipidemia.
Other Criteria	Hyperlipidemia in patients with HeFH without ASCVD - approve if meets all of the following 1. Pt has been diagnosed with HeFH AND 2. tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or Crestor greater than or equal to 20 mg daily) AND 3. LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. Hyperlipidemia Pt with Clinical ASCVD with or without HeFH -approve if meets all of the following has an LDL-C greater than or equal to 70 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 therapy), AND has one of the following conditions prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND tried ONE high intensity statin (as defined above) AND LDL-C remains greater than or equal to 70 mg/dL unless the pt is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. HoFH - approve if meets all of the following has one of the following genetic confirmation of

PA Criteria	Criteria Details
	two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR untreated LDL-C greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents), OR treated LDL-C greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha, Kynamro or Juxtapid), OR have clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND tried ONE high intensity statin (as defined above) for greater than or equal to 8 weeks and LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c.

REVLIMID

Products Affected

- Revlimid

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Revlimid for a Covered Use. Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Follicular Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical).
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and previous therapies or drug regimens tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	MCL-approve if the patient meets one of the following 1) Pt has tried two prior therapies or therapeutic regimens (eg, Velcade, HyperCVAD [cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose mextotrexate and cytarabine] + Rituxan [rituximab injection], the NORDIC regimen [dose-intensified induction immunochemotherapy with Rituxan + cyclophosphamide, vincristine, doxorubicin, prednisone alternating with Rituxan and high-dose cytarabine], RCHOP/RICE [Rituxan, cyclophosphamide, doxorubicin, vincristine, prednisone]/[Rituxan, Ifex (ifosafamide injection), carboplatin, etoposide], Treanda (bendamustine injection) plus Rituxan, Velcade (bortezomib injection) +/- Rituxan, cladribine + Rituxan, FC (fludarabine, cyclophosphamide) +/- Rituxan, PCR [pentostatin, cyclophosphamide, Rituxan]), or Imbruvica (ibrutinib capsules), OR 2) Pt has tried one prior therapy or therapeutic regimen (examples listed above) and cannot take Velcade according to the prescribing physician. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa

PA Criteria	Criteria Details
	injection], Aranesp [darbepoetin alfa injection]). Diffuse, Large B Cell Lymphoma (Non-Hodgkin's Lymphoma)-approve if the pt has tried one other medication treatment regimen (eg, RCHOP, dose-adjusted EPOCH [etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin] + Rituxan, RCEPP [Rituxan, cyclophosphamide, etoposide, prednisone, procarbazine], DHAP [dexamethasone, cisplatin, cytarabine] +/- Rituxan, ICE [Ifex, carboplatin, etoposide] +/- Rituxan, and Treanda +/- Rituxan). Myelofibrosis-approve if the pt has tried one other therapy (eg, Jakafi [ruxolitinib tablets], androgens [eg, nandrolone, oxymetholone], Epogen, Procrit, Aranesp, prednisone, danazol, Thalomid [thalidomide capsules], melphalan, Myleran [busulfan tablets], alpha interferons, and hydroxyurea).

RITUXAN

Products Affected

- Rituxan

PA Criteria	Criteria Details
Covered Uses	All medically-accepted indications not otherwise excluded from Part D. Patients already started on Rituxan for a Covered Use.
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	RA (initial course). Prescribed by a rheumatologist or in consultation with a rheumatologist.
Coverage Duration	RA,3mo. Othr=12 mo.
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. RA (initial course), approve if 1. Rituxan is prescribed in combination with methotrexate or another traditional DMARD (eg, leflunomide or sulfasalazine) unless the patient has been shown to be intolerant or has a contraindication to one or more traditional DMARDs AND 2. the patient has tried one of certolizumab pegol, etanercept, adalimumab, infliximab, golimumab (ie, a TNF antagonist), unless the patient has CHF or a lymphoproliferative disease OR if the patient has not yet tried a TNF antagonist, the patient must have a trial with etanercept or adalimumab.

RUBRACA

Products Affected

- Rubraca oral tablet 200 mg, 250 mg, 300 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Rubraca for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Rubraca is being used. For Ovarian Cancer must have documentation of BRCA-mutation (germline or somatic). Other medications tried for the diagnosis provided
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3years
Other Criteria	Initial Therapy. Approve for 3 years if the patient meets the following criteria (i and ii): i.The patient has a BRCA-mutation (germline or somatic) as confirmed by an approved test, AND ii.The patient has progressed on two or more prior lines of chemotherapy.

RYDAPT

Products Affected

- Rydapt

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on midostaurin for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	For AML, FLT3 status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	AML-approve if the patient is FLT3-mutation positive as detected by an approved test.

SAMSCA

Products Affected

- Samsca

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 30 days
Other Criteria	Hyponatremia - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on Samsca and has received less than 30 days of therapy.

SIGNIFOR

Products Affected

- Signifor

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial therapy - 3 months, Continuation therapy - 3 years
Other Criteria	Cushing's disease, initial therapy - approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushing's disease, continuation therapy - approve if the patient has already been started on Signifor and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.

SPRYCEL

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus GIST and patients already started on Sprycel for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Sprycel is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For CML, new patient must have Ph-positive CML for approval of Sprycel. For ALL, new patient must have Ph-positive ALL for approval of Sprycel. GIST - has D842V mutation AND previously tried Sutent and Gleevec.

STIVARGA

Products Affected

- Stivarga

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Stivarga for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Metastatic CRC, patient must have previously been treated with each of the following for approval: a fluoropyrimidine (eg, Xeloda, 5-FU), oxaliplatin, and irinotecan. If patient's tumor or metastases are wild-type KRAS and/or NRAS (that is, the tumors or metastases are KRAS and/or NRAS mutation negative), approve if Erbitux or Vectibix has been tried. For GIST, patient must have previously been treated with imatinib (Gleevec) and sunitinib (Sutent). For HCC, patient must have previously been treated with Nexavar (sorafenib).

SUTENT

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Sutent for a Covered Use. Advanced, unresectable neuroendocrine tumors, chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and Hurthle) thyroid carcinoma, medullary thyroid carcinoma, thymic carcinoma.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Gastrointestinal stromal tumors (GIST), approve if the patient has previously tried imatinib (Gleevec). Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried chemotherapy (e.g., carboplatin/paclitaxel) or radiation therapy.

SYMDEKO

Products Affected

- Symdeko

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Patients with unknown CFTR gene mutations
Required Medical Information	Diagnosis, specific CFTR gene mutations
Age Restrictions	Twelve years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	3 years
Other Criteria	CF - must have at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A G, S945L, S977F, F1052V, E831X, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G A, 3272-26A G, or 3849 + 10kbC T OR the patient has two copies of the F508del mutation

SYMLIN

Products Affected

- SymlinPen 120
- SymlinPen 60

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D worded as patient has type 1 or 2 diabetes mellitus.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

SYPRINE

Products Affected

- Syprine
- trientine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Syprine for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medication history, pregnancy status, disease manifestations
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For Wilson's Disease, approve if the patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant.

TAFINLAR

Products Affected

- Tafinlar oral capsule 50 mg, 75 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus NSCLC in patients with BRAF V600 E mutation. Plus patients already started on Tafinlar for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tafinlar is being used. BRAF V600 mutations
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For unresectable or metastatic melanoma with BRAF V600 mutation AND used as monotherapy or in combination with Mekinist. For NSCLC, must have BRAF V600E mutation

TAGRISSO

Products Affected

- Tagrisso oral tablet 40 mg, 80 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have EGFR exon 19 deletion or exon 21 (L858R) substitution as detected by an approved test.
Exclusion Criteria	N/A
Required Medical Information	NSCLC - prior therapies and EGFR T790M mutation or EGFR exon 19 deletion or exon 21 (L858R) substitution
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	NSCLC - Must have metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC as detected by an approved test AND hasprogressed on or after one of Tarceva, Iressa, or Gilotrif therapy OR Advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have EGFR exon 19 deletion or exon 21 (L858R) substitution as detected by an approved test.

TARCEVA

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Tarceva for a Covered Use, renal cell carcinoma (RCC).
Exclusion Criteria	N/A
Required Medical Information	Advanced, recurrent, or metastatic non small cell lung cancer (NSCLC), EGFR mutation or gene amplification status.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Metastatic NSCLC, approve if the patient meets both of the following: 1. patient is EGFR mutation positive, AND 2. patient has EGFR exon 19 deletions OR exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Pancreatic locally advanced, unresectable, or metastatic cancer, approve if Tarceva is being prescribed in combination with gemcitabine. Advanced RCC, approve if the patient has non-clear cell histology.

TASIGNA

Products Affected

- Tasigna oral capsule 150 mg, 200 mg, 50 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tasigna for a Covered Use. Plus Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST).
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and ALL, prior therapies tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For CML, new patient must have Ph-positive CML for approval of Tasigna. For GIST, patient must have tried TWO of the following - sunitinib (Sutent), imatinib (Gleevec), or regorafenib (Stivarga). For ALL, Approve if the patient has tried one other tyrosine kinase inhibitors that is used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).

TAZORAC

Products Affected

- tazarotene
- Tazorac

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Cosmetic uses
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PP/acne vulgaris - 3 years, other - 12 months
Other Criteria	Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene).

TECFIDERA

Products Affected

- Tecfidera

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tecfidera for a Covered Use.
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	MS, patient must have a relapsing form of MS (RRMS, SPMS with relapses, or PRMS). MS, previous MS therapies tried.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

THALOMID

Products Affected

- Thalomid

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Thalomid for a Covered Use, Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, Systemic Light Chain Amyloidosis.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Myelofibrosis, approve if the patient has tried one other therapy (eg, ruxolitinib [Jakafi], danazol, epoetin alfa [Epogen/Procrit], prednisone, lenalidomide [Revlimid], hydroxyurea). Prurigo nodularis, approve if the patient has tried two other therapies (eg, azathioprine, capsaicin, psoralen plus ultraviolet A [PUVA] therapy, ultraviolet B [UVB] therapy). Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine).

TOPICAL AGENTS FOR ATOPIC DERMATITIS

Products Affected

- tacrolimus topical

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.

TOPICAL RETINOID PRODUCTS

Products Affected

- adapalene-benzoyl peroxide
- tretinoin topical

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Coverage is not provided for cosmetic use.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	N/A

TOPICAL TESTOSTERONE PRODUCTS

Products Affected

- AndroGel transdermal gel in metered-dose pump 20.25 mg/1.25 gram (1.62 %)
- AndroGel transdermal gel in packet 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)
- testosterone transdermal gel in packet 1 % (25 mg/2.5gram)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. hypogonadism has been confirmed by a low for age serum testosterone (total or free) level defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]

TOPIRAMATE/ZONISAMIDE

Products Affected

- topiramate oral capsule, sprinkle
- topiramate oral tablet
- zonisamide

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Coverage is not provided for weight loss or smoking cessation.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	N/A

TRANSDERMAL FENTANYL

Products Affected

- fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr

PA Criteria	Criteria Details
Covered Uses	All FDA-labeled indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Indication
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Clinical criteria incorporated into the quantity limit edits for transdermal fentanyl products require confirmation the indication is intractable pain (ie, FDA labeled use) prior to reviewing for a quantity exception.

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

- fentanyl citrate

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer pain (ie, FDA labeled use) prior to reviewing for quantity exception.

TYKERB

Products Affected

- Tykerb

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tykerb for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tykerb is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	HER2-positive advanced or metastatic breast cancer, approve if Tykerb will be used in combination with Xeloda or Herceptin and the patient has received prior therapy with Herceptin. HER2-positive HR positive metastatic breast cancer, approve if the patient is a man receiving a LHRH agonist, a premenopausal or perimenopausal woman receiving ovarian suppression/ablation with a LHRH agonist, or a postmenopausal woman and Tykerb will be used in combination with an aromatase inhibitor, that is letrozole (Femara), anastrozole, or elemestane. In this criteria, man/woman is defined as an individual with the biological traits of a man/woman, regardless of the individual's gender identity or expression.

TYMLOS

Products Affected

- Tymlos

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, calcitonin nasal spray [Miacalcin, Fortical, Forteo), except calcium and Vitamin D. Previous use of Tymlos and/or Forteo for a combined total no greater than 2 years duration during a patient's lifetime.
Required Medical Information	Previous medications tried, renal function
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 2 years of therapy over a patient's lifetime
Other Criteria	Treatment of PMO, approve if the patient meets ONE of the following criteria: patient has tried one oral bisphosphonate or cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or patient cannot remain in an upright position post oral bisphosphonate administration or patient has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR patient has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR patient has severe renal impairment or CKD, OR patient has had an osteoporotic fracture or fragility fracture

TYSABRI

Products Affected

- Tysabri

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tysabri for a Covered Use.
Exclusion Criteria	CD - Concurrent Use of Tysabri with an Immunosuppressant Agent in Patients with Crohn's Disease. MS - Current Use of Tysabri with Other Disease-Modifying Agents or immunosuppressants used for MS. Per warning and precautions, coverage is not provided for immune compromised patients with MS or CD.
Required Medical Information	Adults with MS. Patient has a relapsing form of MS (relapsing forms of MS are relapsing remitting [RRMS], secondary progressive [SPMS] with relapses, and progressive relapsing [PRMS]). Adults with CD. Patient has moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein).
Age Restrictions	Adults
Prescriber Restrictions	MS. Prescribed by, or in consultation with, a neurologist or physician who specializes in the treatment of MS.CD. Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	MS-Authorization will be for 3 years.CD, initial-3 mo. CD, cont therapy-3 years.
Other Criteria	Adults with a relapsing form of MS. Patient has had an inadequate response to, or is unable to tolerate, one disease modifying agent used for MS (eg, interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone/Glatopa), Plegridy, fingolimod (Gilenya), Tecfidera, Lemtrada, daclizumab (Zinbryta), Aubagio) OR the patient has highly active or aggressive disease according to the prescribing physician. Adults with CD, initial. Patient has moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein) and patient has tried two of the following agents for CD for at least 2 months each: adalimumab, certolizumab pegol, infliximab, vedolizumab, ustekinzumab, OR pt has had an inadequate response or was intolerant to these agents. CD, continuation therapy. Patient has had a response to Tysabri, as determined by the prescribing physician.

UPTRAVI

Products Affected

- Uptravi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients currently taking Uptravi.
Exclusion Criteria	N/A
Required Medical Information	Confirmation of right heart catheterization (select populations), medication history.
Age Restrictions	N/A
Prescriber Restrictions	PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	3 years
Other Criteria	Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Right heart catheterization is NOT required in pts who are currently receiving Uptravi or another agent indicated for PAH (WHO group 1). Patient must meet a) OR b): a) tried TWO or is currently taking TWO oral therapies for PAH (either alone or in combination) each for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Adcirca, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, Remodulin, or epoprostenol injection).

VENCLEXTA

Products Affected

- Venclexta
- Venclexta Starting Pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients currently taking Venclexta for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	CLL with or without 17p deletion - approve if the patient has tried one prior therapy.

VERZENIO

Products Affected

- Verzenio oral tablet 100 mg, 150 mg, 200 mg, 50 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer in a woman - approve if the patient has advanced or metastatic HR+ [i.e., (ER+) and/or (PR+)], HER2-negative breast cancer and meets all of the following criteria: 1) cancer has progressed during or after endocrine therapy (e.g., anastrozole, exemestane, letrozole, tamoxifen, Fareston [toremifene], exemestane plus Afinitor [everolimus], Faslodex [fulvestrant intramuscular injection], megestrol acetate, fluoxymesterone, high-dose ethinyl estradiol), AND 2) patient is postmenopausal and Verzenio will be used in combination with Faslodex (fulvestrant IM injection) OR patient is premenopausal or perimenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone agonist (eg, leuprolide, triptorelin, goserelin) and Verzenio will be used in combination with Faslodex (fulvestrant IM injection) OR Verzenio will be used as monotherapy and the patient has had prior chemotherapy for metastatic breast cancer. Note: a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression.

VOTRIENT

Products Affected

- Votrient

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, patients already taking Votrient for a Covered Use. Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Dermatofibrosarcoma Protuberans (DFSP), Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST).
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Soft tissue sarcoma other than GIST [angiosarcoma, Pleomorphic rhabdomyosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive, soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma, or other non-lipogenic (non-adipocytic) soft tissue sarcoma], approve. Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has advanced or metastatic disease. Advanced RCC - approve. DFSP - approve if the patient has metastasis. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease OR the patient has complete clinical remission after receiving primary treatment with chemotherapy (e.g., carboplatin with paclitaxel) and/or surgery. GIST - approve if the patient has tried TWO of the following: Gleevec, Sutent, or Strivarga. Medullary Thyroid Carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq).

XALKORI

Products Affected

- Xalkori oral capsule 200 mg, 250 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus soft tissue sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation, Plus peripheral T-Cell Lymphoma - Anaplastic Large Cell Lymphoma (ALCL), Plus NSCLC with high level MET amplification or MET Exon 14 skipping mutation. Plus patients already started on crizotinib for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	For the FDA-approved indication of NSCLC for patients new to therapy, ALK status, high level MET amplification status, MET Exon 14 skipping mutation, and ROS1 rearrangement required. For soft tissue sarcoma IMT, ALK translocation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	NSCLC, patient new to therapy must be ALK-positive, have high level MET amplification, have MET Exon 14 skipping mutation, or have ROS1 rearrangement for approval. For IMT, patient new to therapy must have ALK translocation for approval.

XENAZINE

Products Affected

- tetrabenazine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A

XERMELO

Products Affected

- Xermelo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Initial therapy - approve if the patient meets ALL of the following criteria: 1) patient has been on long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection], Sandostatin LAR Depot [octreotide for injection]) for at least 3 consecutive months, AND 2) while on long-acting SSA therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day, AND 3) Xermelo will be used concomitantly with a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with a long-acting SSA therapy for carcinoid syndrome diarrhea.

XOLAIR

Products Affected

- Xolair

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Seasonal or perennial allergic rhinitis (SAR or PAR).
Exclusion Criteria	N/A
Required Medical Information	Moderate to severe persistent asthma and SAR/PAR, baseline IgE level of at least 30 IU/mL. For asthma, patient has a positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay (eg, immunoCAP, ELISA) or the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). For SAR/PAR, patient has positive skin testing (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach) and/or positive in vitro testing (ie, a blood test for allergen-specific IgE antibodies) for one or more relevant allergens (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach). CIU - must have urticaria for more than 6 weeks, with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) AND must have tried therapy with a leukotriene modifier (e.g., montelukast) with a daily non-sedating H1 antihistamine
Age Restrictions	Moderate to severe persistent asthma-6 years and older. All other diagnoses-12 years and older
Prescriber Restrictions	Moderate to severe persistent asthma/SAR/PAR if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist.
Coverage Duration	Initial tx 4 months, continued tx 12 months
Other Criteria	Moderate to severe persistent asthma approve if pt meets criteria 1 and 2: 1) pt has received at least 3 months of combination therapy with an inhaled corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2) inadequate control demonstrated by

PA Criteria	Criteria Details
	hospitalization for asthma or requirement for systemic corticosteroids to control asthma exacerbation(s). For continued Tx for asthma - must meet specialist criteria and patient has responded to therapy as determined by the prescribing physician. SAR/PAR - approve if pt meets all of the following criteria: 1) pt has tried concurrent therapy with at least one drug from 2 of the following classes: an oral non-sedating or low-sedating antihistamine, a nasal antihistamine, a nasal corticosteroid, or montelukast, AND 2) pt has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy or has contraindications to immunotherapy. For continued tx SAR/PAR - must meet specialist criteria and pt must have responded to therapy as determined by the prescribing physician. For CIU cont tx - must meet specialist criteria and have responded to therapy as determined by the prescribing physician.

XTANDI

Products Affected

- Xtandi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus non-metastatic, castration-resistant prostate cancer, Plus patients already started on Xtandi for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Xtandi is being used. For metastatic castration-resistant prostate cancer, prior therapies tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For metastatic, castration-resistant prostate cancer in patients who are not currently taking Xtandi, the patient must have had a trial with abiraterone (Zytiga) unless the patient is unable to try abiraterone due to a contraindication or severe intolerance (eg, difficulty achieving blood glucose control in patients with diabetes, psychiatric reactions) to prednisone OR the pt is chemotherapy treatment-naive and has visceral metastases (e.g., metastases to lung, liver, or other organs except bone). Note- metastases to the bone is not visceral metastases.

XYREM

Products Affected

- Xyrem

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Medication history
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a sleep specialist physician or a Neurologist
Coverage Duration	12 months.
Other Criteria	For Excessive daytime sleepiness (EDS) in patients with narcolepsy - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dexmethylphenidate, dextroamphetamine), modafinil, or Nuvigil.

ZEJULA

Products Affected

- Zejula

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Zejula for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Recurrent ovarian, fallopian tube, or primary peritoneal cancer - approve if the patient has had a complete or partial response after platinum-based chemotherapy regimen AND Zejula is requested for maintenance treatment.

ZELBORAF

Products Affected

- Zelboraf

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or Hurthle cell) with BRAF-positive disease and patients already started on vemurafenib for a Covered Use.
Exclusion Criteria	Concurrent use with Mekinist.
Required Medical Information	BRAFV600 mutation status required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND Zelboraf will be used as monotherapy (this includes patients who have experienced disease progression on a MEK inhibitor) OR Zelboraf will be used in combination with Cotellic (trametinib). HCL - must have relapsed or refractory disease AND tried at least two therapies for hairy cell leukemia (e.g., cladribine, Nipent, cladribine or Nipent with or without Rituxan).

ZEPATIER

Products Affected

- Zepatier

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Zepatier for a Covered Use.
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin or Sovaldi.
Required Medical Information	Genotype, prior medication therapy, concurrent medications, NS5A polymorphism status, prescriber specialty
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or liver transplant MD.
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

ZYDELIG

Products Affected

- Zydelig

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	CLL/Follicular B-Cell Non-Hodgkin Lymphoma/SLL - approve if the patient has tried one prior therapy.

ZYKADIA

Products Affected

- Zykadia

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus Soft Tissue Sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Plus patients with metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive. Plus patients with NSCLC with ROS1 Rearrangement-First-line therapy.
Exclusion Criteria	N/A
Required Medical Information	Must have metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive or ROS1 Reaarangement. IMT - ALK Translocation status.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

ZYTIGA

Products Affected

- Zytiga oral tablet 250 mg, 500 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus hormone sensitive prostate cancer. Plus, patients already started on Zytiga for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Approve if Zytiga is being used in combination with prednisone.

PART B VERSUS PART D

Products Affected

- Abelcet
- Abraxane
- acetylcysteine
- Actimmune
- acyclovir sodium intravenous solution
- Adriamycin intravenous solution 20 mg/10 mL
- Adrucil intravenous solution 500 mg/10 mL
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 mL, 1.25 mg/3 mL, 2.5 mg /3 mL (0.083 %), 5 mg/mL
- Alimta
- Aliqopa
- AmBisome
- Aminosyn 7 % with electrolytes
- Aminosyn 8.5 %-electrolytes
- Aminosyn II 10 %
- Aminosyn II 15 %
- Aminosyn II 8.5 %
- Aminosyn II 8.5 %-electrolytes
- Aminosyn-HBC 7%
- Aminosyn-PF 10 %
- Aminosyn-PF 7 % (sulfite-free)
- Aminosyn-RF 5.2 %
- amiodarone intravenous solution
- amphotericin B
- aprepitant
- Arranon
- Avastin
- azacitidine
- azathioprine
- azathioprine sodium
- Bavencio
- Beleodaq
- BiCNU
- bleomycin injection recon soln 30 unit
- bortezomib
- budesonide inhalation
- busulfan
- Busulfex
- Cancidas
- carboplatin intravenous solution
- caspofungin
- CellCept Intravenous
- cidofovir
- cisplatin
- cladribine
- clofarabine
- Clolar
- cromolyn inhalation
- cyclophosphamide oral capsule
- cyclosporine intravenous
- cyclosporine modified
- cyclosporine oral capsule
- Cyramza
- cytarabine
- cytarabine (PF) injection solution 2 gram/20 mL (100 mg/mL)
- dacarbazine intravenous recon soln 200 mg
- dactinomycin
- Darzalex
- daunorubicin intravenous solution
- decitabine
- docetaxel intravenous solution 160 mg/16 mL (10 mg/mL), 80 mg/4 mL (20 mg/mL)
- doxorubicin intravenous solution 50 mg/25 mL
- doxorubicin, peg-liposomal
- dronabinol
- Ellence intravenous solution 200 mg/100 mL
- Emend oral capsule
- Emend oral suspension for reconstitution
- Empliciti
- Engerix-B (PF) intramuscular syringe
- Engerix-B Pediatric (PF) intramuscular syringe
- epirubicin intravenous solution 200 mg/100 mL
- Erbitux intravenous solution 100 mg/50 mL
- Erwinaze
- Etopophos
- etoposide intravenous

- Faslodex
- Firmagon kit w diluent syringe
- fludarabine intravenous recon soln
- fluorouracil intravenous solution 5 gram/100 mL
- Folotyn intravenous solution 40 mg/2 mL (20 mg/mL)
- Freamine HBC 6.9 %
- ganciclovir sodium intravenous recon soln
- gemcitabine intravenous recon soln 1 gram
- Gengraf oral capsule 100 mg, 25 mg
- Gengraf oral solution
- Halaven
- Hepatamine 8%
- Herceptin
- idarubicin
- ifosfamide intravenous recon soln 1 gram
- Imfinzi
- Intralipid intravenous emulsion 20 %
- Intralipid intravenous emulsion 30 %
- Intron A injection
- ipratropium bromide inhalation
- irinotecan intravenous solution 100 mg/5 mL
- Istodax
- Jevtana
- Kyprolis
- Lartruvo
- Lioresal intrathecal solution 2,000 mcg/mL, 500 mcg/mL
- melphalan HCl
- methotrexate sodium
- methotrexate sodium (PF)
- methylprednisolone oral tablet
- mitomycin intravenous
- mitoxantrone
- Mustargen
- mycophenolate mofetil
- mycophenolate mofetil HCl
- mycophenolate sodium
- Mylotarg
- Nebupent
- Nephramine 5.4 %
- Nipent
- Nulojix
- ondansetron
- ondansetron HCl oral
- oxaliplatin intravenous recon soln 100 mg
- oxaliplatin intravenous solution 100 mg/20 mL
- paclitaxel
- Perforomist
- Perjeta
- Plenamine
- Prednisone Intensol
- prednisone oral tablet
- Premasol 10 %
- Premasol 6 %
- Prograf intravenous
- Proleukin
- Pulmozyme
- Rapamune oral solution
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL
- Recombivax HB (PF) intramuscular syringe
- Sandimmune oral solution
- Simulect intravenous recon soln 20 mg
- sirolimus
- Sylvant
- Synribo
- tacrolimus oral
- Tecentriq
- thiotepa
- tobramycin in 0.225 % NaCl
- Toposar
- topotecan intravenous recon soln
- Torisel
- Travasol 10 %
- Treanda intravenous recon soln
- Trelstar intramuscular syringe
- Trisenox intravenous solution 2 mg/mL
- TrophAmine 10 %
- Trophamine 6%
- Vectibix intravenous solution 100 mg/5 mL (20 mg/mL)
- Velcade
- vinblastine intravenous solution
- Vincasar PFS intravenous solution 1 mg/mL
- vincristine intravenous solution 1 mg/mL

- vinorelbine intravenous solution 50 mg/5 mL
- Vyxeos
- Xatmep
- Xgeva
- Yervoy intravenous solution 50 mg/10 mL (5 mg/mL)
- Yondelis
- Zaltrap intravenous solution 100 mg/4 mL (25 mg/mL)
- Zanosar
- zoledronic acid intravenous solution
- Zortress

Details

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

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