

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

You will need authorization by BlueCross BlueShield of WNY Retiree Pharmacy PDP (PDP) plan before filling prescriptions for the drugs shown in the chart below. BlueCross BlueShield of WNY 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 Member Services at 1-877-461-9218 (TTY only, call 711). We are open October 1 – March 31 8 a.m. to 8 p.m., 7 days a week and April 1 - September 30 8 a.m. to 8 p.m., Monday - Friday. Calls to these numbers are free. You can also visit our website, www.bcbswny.com/pharmacy

ACTEMRA SQ

Products Affected

- Actemra subcutaneous

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started in tocilizumab (IV/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/GCA/PJIA - Prescribed by or in consultation with a rheumatologist.
Coverage Duration	GCA-6 mo initial, 3 yr cont.PJIA-4 mo initial, 3 yr cont.All other dx-3 mo initial, 3 yr cont.

PA Criteria	Criteria Details
Other Criteria	<p>RA initial - approve if the patient has tried TWO of the following: Enbrel, Humira, Oencia (IV/SC) , or Xeljanz/XR (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the try TWO requirement: Cimzia, infliximab, golimumab SC/IV) OR if, according to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, approve if the patient has tried etanercept, Oencia or adalimumb. (Note: the patient does not have to have a trial with etanercept, Oencia or adalimumb if they have had a trial with infliximab in the past.)</p> <p>Cont tx - pt must have had a response as determined by the prescriber.</p>

ACTHAR

Products Affected

- Acthar H.P.

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Coverage is not provided for diagnostic procedure.
Required Medical Information	Diagnosis, prescriber or consulting physician specialty, previous medications tried and response
Age Restrictions	Infantile spasms- less than 2yo. Acute MS exac-adult
Prescriber Restrictions	Infantile spasms, prescr/consult w/neurolo/epileptologist.MS exacerbation, prescr/consult w/neuro/phys specializes MS.RA, JIA/JRA, AS, PsA, SLE, Systemic Dermatomyositis, prescr/consult w/rheum.Severe Erythema Multiforme, prescr/consult w/derm.Serum Sickness,prescr/consult w/allergist.Severe acute/chronic allergic/inflamm processes of eye and its adnexa, prescr/consult w/ ophthalmologist.Symptomatic Sarcoidosis, prescr/consult w/pulm/cardio.Nephrotic Syndrome, prescr/consult w/nephrologist.
Coverage Duration	All diagnoses-1 month
Other Criteria	For acute MS exacerbation, approve if the patient cannot use high-dose IV corticosteroids because IV access is not possible or if the patient has tried high-dose corticosteroids administered IV for an acute MS exacerbation and has experienced a severe adverse effect or treatment failure AND is NOT being used as pulse therapy on a monthly basis. For all other FDA approved diagnoses (other than Infantile spasms or MS exacerbation), approve if the patient has tried a systemic corticosteroid (oral or IV) for the current condition and patient has experienced a severe adverse effect or treatment failure with the corticosteroid (e.g., a psychotic reaction).

ACYCLOVIR (TOPICAL)

Products Affected

- acyclovir topical
- Zovirax topical ointment
- Zovirax topical cream

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	Zovirax 5% cream, 12 yrs or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	If the request is for brand name Zovirax 5% ointment, the patient is required to have tried generic acyclovir 5% ointment prior to approval.

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 prescribed 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 catheterization is not required in pts who are currently receiving Adempas or another agent indicated for WHO group 1.

AFINITOR

Products Affected

- Afinitor
- Afinitor Disperz

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, Lymphangiomyomatosis, 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, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST) and Recurrent or progressive Meningioma.
Exclusion Criteria	N/A
Required Medical Information	Under CMS Review
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	Under CMS Review

AIMOVIG

Products Affected

- Aimovig Autoinjector (2 Pack)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, number of migraine headaches per month, prior therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Approve if the patient meets the following criteria (A and B)-A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) patient has tried at least two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician.

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 as detected by an approved test.

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. Patients 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

ARANESP

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Anemia due to myelodysplastic syndrome (MDS).
Exclusion Criteria	N/A
Required Medical Information	Anemia w/CRF on and not on dialysis. A hemoglobin (Hb) of less than 10.0 g/dL for adults and less than or equal to 11 g/dL for children required for start, Hb has to be less than or equal 11.5 g/dL adults or less than or equal to 12 g/dL in children if previously receiving epoetin alfa (EA) or Aranesp or less than or equal to 11.5 g/dL in adults currently receiving Mircera. Anemia due to myelosuppressive chemotx, Hb is 10.0 g/dL or less to start or less than or equal to 12.0 g/dL if previously on EA or Aranesp AND currently receiving myelosuppressive chemo. MDS, approve tx if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. If the pt has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL.
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, Other=6 mos.
Other Criteria	For all covered uses, the patient is required to try Procrit first line.

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.

AUBAGIO

Products Affected

- Aubagio

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use of Aubagio 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 1 year.
Other Criteria	For patients already taking Aubagio, approve.

AUSTEDO

Products Affected

- Austedo oral tablet 12 mg, 6 mg, 9 mg

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	Prescribed by or in consultation with a neurologist or a psychiatrist
Coverage Duration	1 year
Other Criteria	N/A

AVONEX

Products Affected

- Avonex (with albumin)
- Avonex intramuscular syringe kit
- Avonex intramuscular pen injector kit

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use of other disease-modifying agent used for multiple sclerosis
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

BENLYSTA

Products Affected

- Benlysta subcutaneous

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with other biologics or with cyclophosphamide intravenous (IV)
Required Medical Information	Diagnosis, medications that will be used in combination, autoantibody status
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation)
Coverage Duration	Initial-4 months, cont-3 years
Other Criteria	<p>Initial-The patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician.</p> <p>Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician AND The patient has responded to Benlysta as determined by the prescriber.</p>

BETASERON/EXTAVIA

Products Affected

- Betaseron subcutaneous kit
- Extavia subcutaneous kit

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 sclerosis
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	For patients requesting Extavia, approve if the patient has tried two of the following: interferon beta-1a intramuscular (Avonex), interferon beta-1a subcutaneous (Rebif), interferon beta-1b (Betaseron), pegylated interferon beta-1a (Plegridy) or glatiramer acetate (Copaxone).

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 Philadelphia chromosome positive Acute Lymphoblastic Leukemia. Plus patients already started on Bosulif for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. For CML/ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies tried.
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).

C1 ESTERASE INHIBITORS

Products Affected

- Berinert intravenous kit
- Cinryze
- Haegarda
- Ruconest

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. Plus Chronic Lymphocytic Leukemia (CLL). Plus Small Lymphocytic Lymphoma (SLL).
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	CLL and SLL-approve if the patient has tried one prior 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.

CIALIS

Products Affected

- Cialis oral tablet 2.5 mg, 5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Indication for which tadalafil is being prescribed.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 mos.
Other Criteria	Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED).

CIMZIA

Products Affected

- Cimzia
- Cimzia Powder for Reconst

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D plus patients already started on certolizumab pegol for Covered use.
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried
Age Restrictions	Adults for CD.
Prescriber Restrictions	RA/AS, prescribed by or in consultation with a rheumatologist. Crohn's disease, prescribed by or in consultation with a gastroenterologist. PsA prescribed by or in consultation with a rheumatologist or dermatologist
Coverage Duration	3 months initial, 3 years cont.
Other Criteria	AS, approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx. PsA, approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx, Stelara, Otezla, Orencia or Xeljanz/XR. RA, approve if the patient has tried two of the following: Enbrel, Humira, Orencia, or Xeljanz/XR. CD, approve if patient has previously tried Humira. Plaque Psoriasis-approve if the patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, or Cosentyx. Cont tx - approve if the patient has had a response to therapy, as according to the prescribing physician

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 20 mg/mL, 40 mg/mL
- Glatopa subcutaneous syringe 20 mg/mL, 40 mg/mL
- glatiramer subcutaneous syringe 20 mg/mL, 40 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 sclerosis
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.

COSENTYX

Products Affected

- Cosentyx (2 Syringes)
- Cosentyx Pen (2 Pens)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Cosentyx for a Covered Use.
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis and previous medications use
Age Restrictions	PP/AS/PsA initial - 18 years of age and older
Prescriber Restrictions	PP initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS initial- by or in consultation with rheumatologist, PsA initial- by or in consultation with rheumatologist or dermatologist.
Coverage Duration	PP/AS - initial tx 3 mos, PsA-initial tx 3 mos, cont tx 3 years
Other Criteria	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 determined by the prescribing physician. PP/AS/PsA cont - patient must have responded, as determined by the prescriber.

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 (unresectable, advanced or metastatic) - 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

DAKLINZA

Products Affected

- Daklinza

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Combination use with Direct Acting Antivirals (DAAs) other than Sovaldi or ribavirin.
Required Medical Information	Hep C genotype, concurrent medications, medication history, treatment naive or experienced, prescriber specialty
Age Restrictions	18 years of age and 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 consistent with current AASLD/IDSA guidance. And, patients with genotype 1 and 4 must have a trial with Harvoni or Epclusa prior to approval of Daklinza, unless Harvoni and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype 2 and 3 must have an Epclusa trial prior to approval of Daklinza, unless Epclusa is not specifically listed as an alternative therapy for a specific patient population in the guidelines.

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	Under CMS Review
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.

DESOXYN

Products Affected

- Desoxyn
- methamphetamine

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

DOPTELET

Products Affected

- Doptelet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, platelet count, date of procedure
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	5 days
Other Criteria	Approve if the patient has a current platelet count less than 50 x 10 ⁹ /L AND the patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy.

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).

EGRIFTA

Products Affected

- Egrifta subcutaneous recon soln 1 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis.
Age Restrictions	Adults
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of HIV (eg, infectious disease, oncology).
Coverage Duration	6 months initial, 3 years cont
Other Criteria	initial HIV-infected adult patients (18 years of age or older) with lipodystrophy AND Egrifta is being used to reduce excessive abdominal fat. Cont - approve if the patient has responded (e.g., reduction in visceral adipose tissue measured by waist circumference or CT scan), as determined by the prescriber. The patient may not have a full response, but there should have been response to Egrifta.

EMFLAZA

Products Affected

- Emflaza

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
Age Restrictions	5 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	N/A

ENBREL

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D plus patient already on etanercept for a Covered Use. Graft versus host disease (GVHD). Behcet's disease. Uveitis
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	N/A
Prescriber Restrictions	RA/Ankylosing spondylitis/JIA/JRA, prescribed by or in consult w/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consult w/ dermatologist. GVHD, prescribed by or in consult w/ oncologist, hematologist, or physician affiliated w/ transplant center. Behcet's disease, prescribed by or in consult w/ rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.
Coverage Duration	FDA approved indications - 3 months initial, 3 years cont, others 12 months.
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, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other agent for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID, biologic DMARD or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide. Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane,

PA Criteria	Criteria Details
	<p>oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD. Tried or currently is receiving with etanercept 1 conventional GVHD tx (high-dose systemic corticosteroid, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Uveitis-tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives, Humira or an infliximab product. RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months.</p>

ENDARI

Products Affected

- Endari

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
Age Restrictions	Greater than or equal to 5 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (e.g., a hematologist)
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A

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 consistent with current AASLD/IDSA guidance.

EPOETIN/PROCRIT

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All 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 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. 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
Other Criteria	For all covered uses, if the request is for Epogen, then the patient is required to try Procrit first line.

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/JADENU

Products Affected

- Exjade
- Jadenu
- Jadenu Sprinkle

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 if 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	N/A

FASENRA

Products Affected

- Fasenra

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody
Required Medical Information	Diagnosis, severity of disease, peripheral blood eosinophil count, previous therapies tried and current therapies, FEV1/FVC
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	Under CMS Review

FERRIPROX

Products Affected

- Ferriprox

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 physician that specializes in the treatment of HAE or related disorders.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

FLECTOR

Products Affected

- Flector

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 mos.
Other Criteria	Patients must try a generic oral NSAID or Voltaren gel.

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 [Fortical], abaloparatide), 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 of therapy over a patient's lifetime
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 an osteoporotic fracture or fragility fracture. 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

PA Criteria	Criteria Details
	CKD or has had an osteoporotic fracture or fragility fracture.

GABAPENTIN/LYRICA

Products Affected

- gabapentin oral capsule 100 mg, 300 mg, 400 mg
- gabapentin oral solution 250 mg/5 mL
- gabapentin oral tablet 600 mg, 800 mg
- Lyrica oral capsule 100 mg, 150 mg, 200 mg, 225 mg, 25 mg, 300 mg, 50 mg, 75 mg
- Lyrica oral solution
- Neurontin oral capsule 100 mg, 300 mg, 400 mg
- Neurontin oral solution
- Neurontin oral tablet 600 mg, 800 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. Plus, patients already started on 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 12 months.
Other Criteria	N/A

GATTEX

Products Affected

- Gattex 30-Vial

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	1 year
Other Criteria	N/A

GILENYA

Products Affected

- Gilenya oral capsule 0.5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use of Gilenya with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	For use in MS, patient has a relapsing form of MS.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A

GILOTRIF

Products Affected

- Gilotrif

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	For NSCLC - EGFR exon deletions or mutations 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 as detected by an approved test. NSCLC metastatic squamous cell must have disease progression with first line treatment with platinum based chemotherapy.

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Products Affected

- Adlyxin subcutaneous pen injector 10 mcg/0.2 mL- 20 mcg/0.2 mL, 20 mcg/0.2 mL
- Bydureon
- Bydureon BCise
- Byetta subcutaneous pen injector 10 mcg/dose(250 mcg/mL) 2.4 mL, 5 mcg/dose (250 mcg/mL) 1.2 mL
- Ozempic subcutaneous pen injector 0.25 mg or 0.5 mg(2 mg/1.5 mL), 1 mg/0.75 mL (2 mg/1.5 mL)
- Tanzeum
- Trulicity
- Victoza 3-Pak

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	N/A

GOCOVRI

Products Affected

- Gocovri oral capsule, extended release
24hr 137 mg, 68.5 mg

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 tried, concurrent medications
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial and continuation).
Coverage Duration	Initial-3 months. Cont-1 year.
Other Criteria	Initial therapy - approve if the following criteria are met: 1) patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa) AND, 2) patient has tried immediate-release amantadine (capsules, tablets, or oral solution) and derived benefit from the immediate-release formulation but had intolerable adverse events or the patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber. Cont. therapy - approve if the patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa) and has had a response to therapy (e.g., decrease in dyskinesia), as determined by the prescriber.

GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

Products Affected

- Eligard
- Eligard (3 month)
- Eligard (4 month)
- Eligard (6 month)
- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)

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	For abnormal uterine bleeding,uterine leiomyomata,endometriosis 6 mo.All other=12 mo
Other Criteria	N/A

GRALISE/HORIZANT/LYRICA CR

Products Affected

- Gralise 30-Day Starter Pack
- Gralise oral tablet extended release 24 hr 300 mg, 600 mg
- Horizant oral tablet extended release 300 mg, 600 mg
- Lyrica CR oral tablet extended release 24 hr 165 mg, 330 mg, 82.5 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	N/A

GRANIX

Products Affected

- Granix

PA Criteria	Criteria Details
Covered Uses	All FDA -approved indications not otherwise excluded from Part D. Plus patients undergoing peripheral blood progenitor cell (PBPC) Collection and Therapy.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Cancer patient receiving chemo-Prescribed by or in consultation with an oncologist, infectious disease specialist, or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist or physician that specializes in transplantation.
Coverage Duration	PBPC-1 month, All others-6 months
Other Criteria	Cancer patients receiving Myelosuppressive Chemotherapy-Must meet ONE of the following - 1. be receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen) 2. be receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (e.g., at least 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, HIV infection) 3. have had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a CSF (e.g., Granix, Neulasta, Zarxio, Neupogen, or Leukine) and a reduced dose or frequency of chemotherapy may compromise treatment OR 4. has received chemotherapy has febrile neutropenia and has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the

PA Criteria	Criteria Details
	prescribing physician (e.g., sepsis syndrome, older than 65 years, severe neutropenia - ANC less than 100 cells/mm ³ , neutropenia expected to be more than 10 days in duration, invasive fungal infection, other clinically documented infections, or prior episode of febrile neutropenia).

GROWTH HORMONES

Products Affected

- Genotropin
- Genotropin MiniQuick
- Humatrope
- Norditropin FlexPro
- Nutropin AQ Nuspin
- Omnitrope
- Saizen
- Saizen saizenprep
- Serostim subcutaneous recon soln 4 mg, 5 mg, 6 mg
- Zomacton
- Zorbtive

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>HIV initial-1.wasting/cachexia due to malabsorption, poor diet, opportunistic infx, depression and other causes which have been addressed prior to starting tx, 2.on antiretroviral or HAART or more than 30 days and will cont throughout Serostim tx, 3.not being used for alternations in body fat distribution (abdom girth, liopdytrophy, buffalo hump, excess abdm fat), AND 4. unintentional wt loss greater than 10 percent from baseline, wt less than 90 percent of lower limit of IBW, or BMI less than or equal to 20 kg/m2.HIV Cont tx -meets initial tx criteria.GHD in children/adolescents initial must meet ONE of the following-1.had hypophysectomy,2.has congenital hypopit AND GH response to one preferred GH test of less than 10 ng/mL (preferred tests levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon),3.panhypopit AND had GH response to one preferred GH test of less than 10 ng/mL, has 3 or more pit hormone def(ACTH, TSH, LH/FSH, or prolactin), or pit stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior "bright spot" on MRI or CT, 4. brain rad, had GH response to one preferred GH test of less than 10 ng/mL, AND meets one of these a. pretxgrowth 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 GH 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. pretx 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.</p>
Age Restrictions	ISS 5 y/o or older, SGA 2 y/o or older, SBS and HIV wasting/cachexia 18 y/o or older

PA Criteria	Criteria Details
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 initial, 12 months cont tx, SBS 4 weeks, HIV 24 weeks, others 12 mos
Other Criteria	Under CMS Review

HARVONI

Products Affected

- Harvoni

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with recurrent HCV post-liver transplant. Plus patients started on Harvoni for a covered use
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	N/A
Age Restrictions	12 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a 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.

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

- Ativan oral tablet 0.5 mg, 1 mg, 2 mg
- clonazepam oral tablet 0.5 mg, 1 mg, 2 mg
- clonazepam oral tablet, disintegrating 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, 2 mg
- clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg
- Diazepam Intensol
- diazepam oral solution 5 mg/5 mL (1 mg/mL)
- diazepam oral tablet
- Klonopin oral tablet 0.5 mg, 1 mg, 2 mg
- lorazepam oral concentrate
- lorazepam oral tablet 0.5 mg, 1 mg, 2 mg
- Onfi oral suspension
- Onfi oral tablet 10 mg, 20 mg
- Tranxene T-Tab oral tablet 7.5 mg
- Valium

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
- Fexmid

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 of promethazine and hydroxyzine, approve if 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
- amoxapine
- Anafranil
- clomipramine
- desipramine
- doxepin oral
- imipramine HCl
- imipramine pamoate
- Norpramin oral tablet 10 mg, 25 mg
- nortriptyline
- Pamelor
- Surmontil
- Tofranil
- 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 or trazodone. For the treatment of pain, may approve amitriptyline (single-entity only, not amitriptyline combination products), desipramine, nortriptyline or imipramine (brand or generic) if the patient has tried at least two of the following agents: duloxetine, pregabalin, gabapentin, venlafaxine or venlafaxine Er. For the treatment of obsessive compulsive disorder (OCD), may approve clomipramine (brand or generic) or desipramine (brand or generic) if the patient has tried at least one 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

PA Criteria	Criteria Details
	requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.

HIGH RISK MEDICATIONS- ESTROGENS

Products Affected

- Activella
- Alora
- Amabelz
- Angeliq
- Climara
- Climara Pro
- CombiPatch
- Divigel transdermal gel in packet 1 mg/gram (0.1 %)
- Elestrin
- Estrace oral
- estradiol oral
- estradiol transdermal patch semiweekly
- estradiol transdermal patch weekly
- estradiol-norethindrone acet
- estropipate oral tablet 0.75 mg, 1.5 mg
- Evamist
- Femhrt Low Dose
- Fyavolv
- Jinteli
- Menest oral tablet 0.3 mg, 0.625 mg, 1.25 mg
- Menostar
- Mimvey
- Mimvey Lo
- Minivelle
- norethindrone ac-eth estradiol oral tablet 0.5-2.5 mg-mcg, 1-5 mg-mcg
- Prefest
- Premphase
- Prempro
- Vivelle-Dot

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 65 years and older
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): Estradiol Vaginal Cream, Premarin Vaginal Cream, Vagifem, Estring, Femring, 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 or Raloxifene. For

PA Criteria	Criteria Details
	the treatment of Vasomotor Symptoms of Menopause, approve if the patient has tried one of the following products: Femring, Estradiol valerate or depo-estradiol. 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/0.2 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

PA Criteria	Criteria Details
	<p>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 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 ileocolonic 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.</p>

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 for patients who have not had disease progression while on Ibrance, Kisqali or Verzenio 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 GnRH agonists, or has had 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 GnRH agonist AND Ibrance with be used as first line endocrine therapy in combination with anastrozole, exemestane, tamoxifen or letrozole, 4. Pt is postmenopausal and has relapsed or progressed during endocrine therapy with at least one of the following: anastrozole, exemestane, letrozole, tamoxifen ,Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone or ethinyl estradiol AND will be used in combination with Faslodex, 5. Pt is premenopausal or perimenopausal

PA Criteria	Criteria Details
	and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation, relapsed or progressed on prior endocrine therapy with at least one of the following: anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone, or ethinyl estradiol AND will be used in combination with 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-positive or has tried TWO other TKIs indicated for use in Ph+ ALL (e.g. Gleevec, Sprycel.)

IDHIFA

Products Affected

- Idhifa

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

IMATINIB

Products Affected

- Gleevec oral tablet 100 mg, 400 mg
- imatinib oral tablet 100 mg, 400 mg

PA Criteria	Criteria Details
Covered Uses	Under CMS Review
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	GVHD-1 year, all others-3 years.
Other Criteria	Under CMS Review

IMBRUVICA

Products Affected

- Imbruvica oral capsule 140 mg, 70 mg
- Imbruvica oral tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus relapsed or refractory Central Nervous System Lymphoma (Primary). Plus relapsed or refractory Hairy Cell Leukemia. Plus Diffuse Large B-Cell Lymphoma (e.g., follicular lymphoma, gastric MALT lymphoma, nongastric MALT lymphoma, primary DLBCL of the central nervous system). 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	GVHD-1 year, all others-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. GVHD- Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, imatinib). Diffuse large B-cell lymphoma-approve if the patient is using Imbruvica as second-line or subsequent therapy according to the prescribing physician.

INGREZZA

Products Affected

- Ingrezza

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	Prescribed by or in consultation with a neurologist or psychiatrist
Coverage Duration	1 year
Other Criteria	N/A

INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- Aveed
- Depo-Testosterone
- testosterone cypionate
- testosterone enanthate

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab results
Age Restrictions	Delayed puberty or induction of puberty in males-14 years and older
Prescriber Restrictions	N/A
Coverage Duration	Delayed puberty or induction of puberty in males-6 months, all others-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 (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. Delayed puberty or induction of puberty in males - Approve testosterone cypionate or testosterone enanthate. Palliative treatment of inoperable metastatic breast cancer in females. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression

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

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

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	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 pt's home.

JAKAFI

Products Affected

- Jakafi

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

JUXTAPID

Products Affected

- Juxtapid

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Combination use with Kynamro, Praluent, or Repatha.
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, an endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders.
Coverage Duration	12 months
Other Criteria	Patient must meet ALL of the following criteria: 1) Patient has had genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B APOB, PCSK9, or LDLRAP1 gene locus OR the patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha or Kynamro) OR the patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) Patient has tried Repatha and had an inadequate response according to the prescribing physician OR the patient is known to have two LDL-receptor negative alleles, AND 3) Patient has tried one high-intensity statin therapy (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than 20 mg daily [as a single-entity or as a combination product]) for greater than or equal to 8 continuous weeks and the LDL-C level remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or patient experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.

JYNARQUE

Products Affected

- Jynarque

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Patient is currently receiving Samsca (tolvaptan tablets) . Patients with Stage 5 CKD
Required Medical Information	Diagnosis, renal function
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	1 year (initial and continuation)
Other Criteria	Approve if the patient has rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]),according to the prescriber.

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 or Symdeko
Required Medical Information	N/A
Age Restrictions	two 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 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.

KEVEYIS

Products Affected

- Keveyis

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 condition, prior medications tried and results, potassium levels
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial 2 months, cont 12 months.
Other Criteria	HypoPP and Related Variants initial must meet all - 1. HypoPP has been confirmed by one of the following - serum potassium concentration of less than 3.5 mEq/L during a paralytic attack, family history of the condition, or a genetically confirmed skeletal muscle calcium or sodium channel mutation, 2. had improvements in paralysis attack symptoms with potassium intake, and 3. tried oral acetazolamide therapy, and 4. according to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient. HyperPP and Related Variants initial must meet all - 1. HyperPP has been confirmed by one of the following - an increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack, serum potassium concentration during a paralytic attack of greater than 5.0 mEq/L, a family history of the condition, or genetically confirmed skeletal muscle sodium channel mutation, 2. prescribing physician has excluded other reasons for acquired hyperkalemia (e.g., drug abuse, renal and adrenal dysfunction), 3. tried oral acetazolamide therapy, 4. according to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient. Cont tx HypoPP and HyperPP - patient has responded to Keveyis (e.g., decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician.

KEVZARA

Products Affected

- Kevzara subcutaneous syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Initial-3 months, cont-3 years
Other Criteria	RA initial - approve if the patient has tried TWO of the following: Enbrel, Humira, Orencia (IV/SC) , or Xeljanz/XR (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Cimzia, an infliximab product, golimumab SC/IV, Actemra, Rituxan or Kineret) OR if, according to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx - pt must have had a response as determined by the prescriber.

KINERET

Products Affected

- Kineret

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D plus patient already started on anakinra for a covered use. Still's disease (SD). Juvenile Rheumatoid Arthritis.
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	N/A
Prescriber Restrictions	RA and Still's disease, prescribed by or in consultation with a rheumatologist. CAPS (Neonatal-Onset Multisystem Inflammatory Disease or Chronic Infantile Neurological Cutaneous and Articular [CINCA] syndrome), prescribed by or in consultation with a pediatrician, rheumatologist, geneticist, or dermatologist.
Coverage Duration	RA/CAPS initial 3 mos, cont 3 years. Stills 12 mos
Other Criteria	RA initial. Approve if the patient has tried TWO of the following: Enbrel, Humira, Orencia (IV/SC), or Xeljanz/XR. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Actemra, Cimzia, infliximab, golimumab IV/SC.] RA/CAPS cont tx - approve if the patient had responded to therapy as determined by the prescriber. Still's Disease, approve if patient has tried a corticosteroid and has had an inadequate response to 1 conventional synthetic DMARD (eg, methotrexate) for at least 2 months or was intolerant to this therapy.

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 in patients who have not had disease progression while on Kisqali, Ibrance or Verzenio 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 GnRH agonist, or has had 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 GnRH agonist AND Kisqali with be used as first line endocrine therapy in combination with anastrozole, exemestane, tamoxifen or letrozole. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane, letrozole or tamoxifen.

KORLYM

Products Affected

- Korlym

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients with Endogenous Cushing's Syndrome, awaiting surgery.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior surgeries
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome
Coverage Duration	Authorization will be for 3 years
Other Criteria	Approve if, according to the prescribing physician, the patient is not a candidate for surgery or surgery has not been curative AND if Korlym is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance.

KUVAN

Products Affected

- Kuvan

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Under CMS Review
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)
Coverage Duration	Initial-12 weeks, Continuation-1 year
Other Criteria	Under CMS Review

KYNAMRO

Products Affected

- Kynamro

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Combination use with Juxtapid, Praluent, or Repatha.
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, an endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders.
Coverage Duration	12 months
Other Criteria	Patient must meet ALL of the following criteria: 1) Patient has had genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B APOB, PCSK9, or LDLRAP1 gene locus OR the patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha or Juxtapid) OR the patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) Patient has tried Repatha and had an inadequate response according to the prescribing physician OR the patient is known to have two LDL-receptor negative alleles, AND 3) Patient has tried one high-intensity statin therapy (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than 20 mg daily [as a single-entity or as a combination product]) for greater than or equal to 8 continuous weeks and the LDL-C level remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or patient experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.

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, Cabometyx) 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. PAH-pt must have tried Opsumit or Letairis prior to approval of Tracleer.

LIDODERM

Products Affected

- lidocaine topical adhesive patch,medicated
- Lidoderm

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

Products Affected

- Belbuca
- buprenorphine transdermal patch weekly 10 mcg/hour, 15 mcg/hour, 20 mcg/hour, 5 mcg/hour
- Butrans
- ConZip
- Dolophine oral tablet 10 mg, 5 mg
- Embeda oral capsule,oral only,ext.rel pell
- Exalgo ER
- hydromorphone oral tablet extended release 24 hr
- Hysingla ER
- Kadian oral capsule,extend.release pellets 10 mg, 100 mg, 20 mg, 200 mg, 30 mg, 40 mg, 50 mg, 60 mg, 80 mg
- methadone oral solution 10 mg/5 mL, 5 mg/5 mL
- methadone oral tablet 10 mg, 5 mg
- morphine oral capsule, ER multiphase 24 hr
- morphine oral capsule,extend.release pellets
- morphine oral tablet extended release 100 mg, 15 mg, 200 mg, 30 mg, 60 mg
- MS Contin
- Nucynta ER
- oxycodone oral tablet,oral only,ext.rel.12 hr 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg
- OxyContin oral tablet,oral only,ext.rel.12 hr 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg
- oxymorphone oral tablet extended release 12 hr
- tramadol oral capsule,ER biphasic 24 hr 17-83
- tramadol oral capsule,ER biphasic 24 hr 25-75 100 mg, 200 mg
- tramadol oral tablet extended release 24 hr
- tramadol oral tablet, ER multiphase 24 hr
- Xtampza ER
- ZOHYDRO ER CAPSULE, ORAL ONLY, ER 12HR

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, AND Nucynta ER for the management of neuropathic pain associated with diabetic peripheral neuropathy.
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	N/A

PA Criteria	Criteria Details
Restrictions	
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), 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	N/A

LYNPARZA

Products Affected

- Lynparza oral capsule
- Lynparza oral tablet

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 confirmed by an approved test AND as per product labeling, has progressed on three or more prior lines of chemotherapy. Breast Cancer- Approve if the patient meets the following criteria (A, B, C, and D)-A. The patient has metastatic, germline BRCA mutation-positive breast cancer AND B. The patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND C. The patient meets ONE of the following criteria (i or ii)- i. The patient meets BOTH of the following criteria (a and b)-a) The patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease AND b) The patient meets ONE of the following criteria (1 or 2)-1- The patient has been treated with prior endocrine therapy OR-2 The patient is considered inappropriate for endocrine therapy OR ii. Patient has triple negative disease (i.e., ER-negative, PR-negative, and HER2-negative) AND D. The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting.

MAVYRET

Products Affected

- Mavyret

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Mavyret for a Covered Use.
Exclusion Criteria	N/A
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	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1, 4, 5 and 6 must have a trial with Harvoni or Epclusa prior to approval of Mavyret, unless Harvoni and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype 2 and 3 must have an Epclusa trial prior to approval of Mavyret, unless Epclusa is not specifically listed as an alternative therapy for a specific patient population in the guidelines.

MEGACE

Products Affected

- Megace ES
- 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 already started on Mekinist for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Melanoma must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC requires BRAF V600E Mutation and use in combination with Tafinlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafinlar, unless intolerant AND the patient has BRAF V600-positive disease.

MEMANTINE

Products Affected

- memantine oral capsule, sprinkle, ER 24hr
- memantine oral solution
- memantine oral tablet
- memantine oral tablets, dose pack
- Namenda oral tablet
- 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 AND as per product labeling, patient cannot be well-controlled on calcium supplements and active forms of vitamin D alone. Chronic hypoparathyroidism, continuing therapy - approve if all of the following are met: 1)the patient cannot be well-controlled on calcium supplements and active forms of vitamin D alone, AND 2) during Natpara therapy, the patient's 25-hydroxyvitamin D stores are sufficient per the prescribing physician, AND 3) 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	Under CMS Review
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 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,

PA Criteria	Criteria Details
	<p>prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver or 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 count less than 100 cells/mm³], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).</p>

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.

NOCTIVA

Products Affected

- Noctiva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Currently receiving loop diuretics, systemic or inhaled glucocorticoids OR renal impairment with an estimated glomerular filtration rate less than 50 mL/min/1.73 per meter squared OR New York Heart Association (NYHA) Class II to IV congestive heart failure (CHF) OR polydipsia OR known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion
Required Medical Information	Diagnosis, lab values, other medications that will be used in combination
Age Restrictions	50 years or older
Prescriber Restrictions	Prescribed by or in consultation with a urologist, a geriatrician, or an endocrinologist
Coverage Duration	12 months
Other Criteria	Prior to desmopressin therapy, the patient awakens at least two times per night to void AND the patient has serum sodium concentrations within the normal range (135 to 145 mmol/L) AND the diagnosis of nocturnal polyuria has been confirmed with a 24-hour urine collection before treatment initiation and the patient meets one of the following (i or ii): i. The nocturnal urine volume exceeds 20% of the total 24-hour urine volume in patients less than 65 years of age OR ii. The nocturnal urine volume exceeds 33% of the total 24-hour urine volume in patients greater than or equal to 65 years of age.

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 (Parkinson's 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 or another Anti-Interleukin (IL) Monoclonal Antibody.
Required Medical Information	N/A
Age Restrictions	Asthma-12 years of age and older. EGPA-18 years of age and older.
Prescriber Restrictions	Asthma-Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA-prescribed by or in consultation with an allergist, immunologist, pulmonologist or rheumatologist.
Coverage Duration	Authorization will be for 6 months initial, 12 months continuation.
Other Criteria	Asthma initial - must have blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks (prior to treatment with any anti-interleukin (IL)-5 therapy) 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. EGPA initial-patient has/had a blood eosinophil

PA Criteria	Criteria Details
	level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL)-5 therapy (e.g., Nucala, Cinqair, Fasenra). Continuation-The patient has responded to Nucala therapy as determined by the prescribing physician (e.g., reduced rate of relapse, corticosteroid dose reduction, reduced eosinophil levels).

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	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	N/A

NUPLAZID

Products Affected

- Nuplazid oral tablet 17 mg

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	1 year
Other Criteria	N/A

NUVIGIL/PROVIGIL

Products Affected

- armodafinil
- modafinil
- Nuvigil
- Provigil

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 (modafinil only) 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	Initial 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 if the 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. Metastatic 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.

OLUMIANT

Products Affected

- Olumiant

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with other biologics, DMARDs, or other potent immunosuppressants
Required Medical Information	Diagnosis, previous medication use, concurrent medication
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist
Coverage Duration	Initial - 3 months, continuation - 3 years
Other Criteria	Initial therapy - approve if the patient has tried TWO of the following: Enbrel, Humira, Orencia (IV/SC), or Xeljanz/XR. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the try TWO requirement: Actemra IV/SC, Cimzia, infliximab, Simponi golimumab IV/SC, Kevzara, Kineret, and Rituxan.] Continuation therapy - approve if the patient has had a response, as determined by the prescriber.

OPSUMIT

Products Affected

- Opsumit

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 catheterization
Age Restrictions	N/A
Prescriber Restrictions	PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1 patients not currently on Opsumit 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 Opsumit or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization.

ORALAIR

Products Affected

- Oralair sublingual tablet 300 indx reactivity

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	The patient is NOT currently receiving SC or SL allergen immunotherapy
Required Medical Information	Diagnosis
Age Restrictions	10 years through 65 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Under CMS Review

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. PsA-prescribed by or in consultation with a rheumatologist or dermatologist.
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. Cont tx - responded to therapy as per the prescriber.

ORENITRAM

Products Affected

- Orenitram

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 must be prescribed 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 catheterization is not required in pts who are currently receiving Orenitram or another agent indicated for WHO group 1. For initial Orenitram therapy, patient must have either A) tried TWO or is currently receiving TWO oral therapies for PAH from different categories (either alone or in combination) each for greater than or equal to 60 days - phosphodiesterase type 5 (PDE5) inhibitor (eg, sildenafil, Adcirca), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit] or Adempas OR B) is receiving or has received in the past one prostacyclin therapy (eg, Ventavis or epoprostenol injection).

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	Under CMS Review
Prescriber Restrictions	prescribed by or in consultation 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)

OTEZLA

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients currently taking Otezla for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous drugs tried
Age Restrictions	N/A
Prescriber Restrictions	PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist.
Coverage Duration	4 months initial, 3 years cont
Other Criteria	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 determined by the prescribing physician. PsA initial-approve if the patient has tried at least one conventional synthetic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant (note: pts who have already tried a biologic DMARD are not required to 'step back' and try a conventional DMARD first). PsA/PP cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician.

PALYNZIQ

Products Affected

- Palyntiq subcutaneous syringe 10 mg/0.5 mL, 2.5 mg/0.5 mL, 20 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	Diagnosis, phenylalanine concentrations
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	1 year (initial and continuation)
Other Criteria	Initial therapy - approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., restriction of dietary phenylalanine and protein intake, prior treatment with Kuvan). Maintenance therapy - approve if the patient's blood phenylalanine concentration is less than or equal to 600 micromol/L OR the patient has achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline.

PHEOCHROMOCYTOMA

Products Affected

- Demser
- Dibenzyline
- phenoxybenzamine

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior medication trials
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial therapy for phenoxybenzamine, initial and continuation therapy for Demser)
Coverage Duration	Authorization will be for 1 year
Other Criteria	If brand Dibenzyline is being requested, approve if the patient has tried and cannot take generic phenoxybenzamine due to a formulation difference in the inactive ingredients between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction. If the requested drug is Demser for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin) AND the patient has tried phenoxybenzamine (brand or generic). If the requested drug is Demser for continuation therapy, approve if the patient is currently receiving Demser or has received Demser in the past.

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

- Adcirca
- Revatio oral suspension for reconstitution
- Revatio oral tablet
- 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 1 patients 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.

PLEGRIDY

Products Affected

- Plegridy subcutaneous pen injector 125 mcg/0.5 mL, 63 mcg/0.5 mL- 94 mcg/0.5 mL
- Plegridy subcutaneous syringe 125 mcg/0.5 mL, 63 mcg/0.5 mL- 94 mcg/0.5 mL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	For use in MS, patient has a relapsing form of MS.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

POMALYST

Products Affected

- Pomalyst

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus Myelofibrosis and Systemic Light Chain Amyloidosis
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years
Other Criteria	N/A

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 -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 - approve if meets all of the following: 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.

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 [Fortical]), abaloparatide 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	Under CMS Review

PROMACTA

Products Affected

- Promacta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
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 mm ³) 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 mm ³) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate mofetil, sirolimus)

REBIF

Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients who experienced 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

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 with HeFH - approve if: 1) diagnosis of 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 LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the symptoms resolved upon discontinuation. Hyperlipidemia with ASCVD -approve if: 1) 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 2) tried ONE high intensity statin (defined above) and LDL remains 70 mg/dL or higher unless pt is statin intolerant (defined above). HoFH - approve if: 1) has one of the following: a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha, Kynamro or Juxtapid), OR d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity statin

PA Criteria	Criteria Details
	<p>(defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if all of the following are met: 1) coronary artery calcium or calcification (CAC) score 300 Agatston units or higher, AND 2) tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above).</p>

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 OR 2) Pt has tried one prior therapy or therapeutic regimen 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 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. Myelofibrosis-approve if the pt has tried one other therapy.

RUBRACA

Products Affected

- Rubraca

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. BRCA-mutation (germline or somatic) status. 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-treatment. 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. Recurrence, Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-i. The patient is in a complete response or a partial response to platinum-based 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.

SILIQ

Products Affected

- Siliq

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Siliq for a covered use.
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Previous medication use
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial therapy - 3 months, Continuation therapy - 3 years
Other Criteria	Initial therapy-Plaque Psoriasis-Approve if the patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, or Cosentyx. Continuation Therapy - Patient must have responded, as determined by the prescriber.

SIMPONI

Products Affected

- Simponi

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on golimumab (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 therapies tried.
Age Restrictions	N/A
Prescriber Restrictions	RA/Ankylosing spondylitis, prescribed by or in consultation with a rheumatologist. Psoriatic arthritis, prescribed by or in consultation with a rheumatologist or dermatologist. UC-prescribed by or in consultation with a gastroenterologist
Coverage Duration	3 mos initial, 3 years cont
Other Criteria	AS approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx. PsA-approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx, Stelara, Otezla, Orencia, Xeljanz/XR. RA, approve if the patient has tried two of the following: Enbrel, Humira, Orencia, or Xeljanz/XR. Ulcerative colitis - approve if the patient has had a trial with Humira. Cont tx - must have a response to therapy as according to prescriber

SOLARAZE

Products Affected

- diclofenac sodium topical gel 3 %

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 6 months.
Other Criteria	Under CMS Review

SOVALDI

Products Affected

- Sovaldi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Sovaldi for a covered use. Plus Recurrent HCV Post-Liver Transplantation genotypes 1, 2, 3, and 4.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Genotype 1 and 4 -18 years or older, Genotype 2 and 3-12 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a 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. And, patients with genotype 1 and 4 must have a trial with Harvoni or Epclusa prior to approval of Sovaldi, unless Harvoni and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Patients with Genotype 2 and 3 must have a trial of Epclusa prior to approval of Sovaldi, unless Epclusa is not specifically listed as an alternative therapy for a specific patient population in the guidelines. Patients with Genotype 2 or 3, who are greater than or equal to 12 but less than 18 are not required to try Epclusa prior to approval of Sovaldi.

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.

STELARA

Products Affected

- Stelara subcutaneous

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus approve Stelara SC in patients already started on Stelara (IV/SC) for a Covered Use.
Exclusion Criteria	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	Adults-PsA and CD. PP-12 years and older.
Prescriber Restrictions	Plaque psoriasis.Prescribed by or in consultation with a dermatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. CD-prescribed by or in consultation with a gastroenterologist.
Coverage Duration	PP/PsA Init-3mo,CD load-approve 1 dose IV,CD post IV load-approve SC 3 mo,cont tx-approve SC 3 yr
Other Criteria	PP initial - approve Stelara SC. CD, induction therapy - approve single dose of IV formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumb, infliximab). CD, initial therapy (only after receiving single IV loading dose) - approve 3 months of the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD. PP/PsA/CD cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy.

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	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

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, meningioma, 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 Sutent will be used as a single agent and the patient has previously tried imatinib (Gleevec) OR Sutent will be used in combination with Afinitor AND the patient has tried TWO of the following: imatinib, Sutent, or Stivarga. 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 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 Trientine 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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with Differentiated Thyroid Cancer. 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	Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC, must have BRAF V600E mutation. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease.

TAGRISO

Products Affected

- Tagrisso

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
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 has progressed 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.

TALTZ

Products Affected

- Taltz Autoinjector
- Taltz Syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients currently receiving Taltz for a Covered Use.
Exclusion Criteria	Concurrent use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis, Previous medication use
Age Restrictions	18 years of age and older
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist. PsA prescribed by or in consultation with a rheumatologist or a dermatologist.
Coverage Duration	Initial authorization will be for 3 months, 3 years continuation.
Other Criteria	Initial Therapy - Plaque Psoriasis-approve if the patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, or Cosentyx. PsA- Approve if the patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, Orencia, Xeljanz/XR or Cosentyx. Continuation Therapy - approve if the patient has responded, as determined by the prescriber.

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 Renal Cell Carcinoma and Bone Cancer-Chordoma. Plus patients already started on Tarceva for a Covered Use.
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. Advanced RCC, approve if the patient has non-clear cell histology.

TARGRETIN ORAL

Products Affected

- bexarotene
- Targretin

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	3 years
Other Criteria	<p>Initial therapy- approve if the following criteria are met: Patient has tried ONE oral retinoid, methotrexate, or phototherapy. (NOTE: An exception to the requirement for a trial of an oral retinoid, methotrexate, or phototherapy can be made if the patient has already used one of the following: interferons, histone deacetylase [HDAC] inhibitors, or extracorporeal photopheresis. These patients are not required to step back and try an oral retinoid, methotrexate, or phototherapy) OR the patient has a type of CTCL (e.g., folliculotropic disease, advanced disease) that, according to the prescribing physician, requires treatment with oral bexarotene capsules. If brand Targretin is requested, the patient has tried and cannot take generic bexarotene capsules due to a formulation difference in the inactive ingredient(s) between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction. Continuation therapy- approve if brand Targretin is requested, the patient has tried and cannot take generic bexarotene capsules due to a formulation difference in the inactive ingredient(s) between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction.</p>

TARGRETIN TOPICAL

Products Affected

- Targretin

PA Criteria	Criteria Details
Covered Uses	Under CMS Review
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	3 years
Other Criteria	Initial therapy-approve if the patient has tried a topical corticosteroid and topical imiquimod cream (Aldara, generics, Zyclara). (NOTE: An exception to the requirement for a trial of a topical corticosteroid and topical imiquimod cream can be made if the patient has already used one of the following: a skin-directed therapy, e.g., topical chemotherapy, topical retinoids, local radiation, phototherapy [UVB, NB-UVB, PUVA], TSEBT, or a systemic therapy, e.g., oral retinoids, interferons, histone deacetylase [HDAC] inhibitors, extracorporeal photopheresis, methotrexate, systemic chemotherapeutic agents. These patients are not required to step back and try a topical corticosteroid and topical imiquimod cream).

TASIGNA

Products Affected

- Tasisna 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 Tasisna 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 Tasisna 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 Tasisna. 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 inhibitor that is used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).

TAVALISSE

Products Affected

- Tavalisse

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies or surgeries
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by, or in consultation with a hematologist
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Approve if the patient has tried one other therapy or the patient has undergone splenectomy.

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.
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 1 year.
Other Criteria	N/A

TECHNIVIE

Products Affected

- Technivie

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Technivie for a Covered Use.
Exclusion Criteria	Combination use with Direct Acting Antivirals (DAAs) other than ribavirin.
Required Medical Information	Hep C genotype, concurrent medications, medication history
Age Restrictions	18 years of age and 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 consistent with current AASLD/IDSA guidance. And, patients with genotype 4 must have a trial with Harvoni or Epclusa prior to approval of Technivie, unless Harvoni and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines.

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

- Elidel
- Eucrisa
- Protopic
- 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 ALPHA-ADRENERGIC AGENTS FOR ROSACEA

Products Affected

- Mirvaso topical gel with pump

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Use in the treatment of erythema not caused by rosacea (ie, transient) [eg, during times of stress, sunburn, or skin irritation from cosmetic products].
Required Medical Information	N/A
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

TOPICAL RETINOID PRODUCTS

Products Affected

- adapalene topical cream
- adapalene topical gel
- adapalene-benzoyl peroxide
- Atralin
- Avita topical cream
- Avita topical gel
- clindamycin-tretinoin
- Differin topical cream
- Differin topical gel 0.1 %
- Differin topical gel with pump
- Differin topical lotion
- Epiduo Forte
- Epiduo topical gel with pump
- Retin-A
- Retin-A Micro
- Retin-A Micro topical gel with pump 0.06 % , 0.08 %
- tretinoin microspheres topical gel
- tretinoin topical
- Ziana

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

- Androderm
- AndroGel transdermal gel in metered-dose pump 20.25 mg/1.25 gram (1.62 %)
- AndroGel transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram), 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)
- Fortesta
- Striant
- Testim
- testosterone transdermal gel in metered-dose pump 10 mg/0.5 gram /actuation
- testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %)
- testosterone transdermal gel in packet
- testosterone transdermal solution in metered pump w/app
- Vogelxo transdermal gel in metered-dose pump
- Vogelxo transdermal gel in packet

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

PA Criteria	Criteria Details
	<p>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. For patients requesting Fortesta, Striant, testosterone (brand), Androgel 1%, Vogelxo, or Testim, approve if the patient has previously tried Androgel 1.62%. Patients who have tried generic Androgel in the past do not need to try brand Androgel prior to approval of the requested drug. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]</p>

TOPIRAMATE/ZONISAMIDE

Products Affected

- Qudexy XR
- Topamax
- topiramate oral capsule, sprinkle
- topiramate oral capsule, sprinkle, ER 24hr
- topiramate oral tablet
- Trokendi XR
- Zonegran oral capsule 100 mg, 25 mg
- 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 3 years.
Other Criteria	N/A

TRANSDERMAL FENTANYL

Products Affected

- Duragesic
- fentanyl

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Acute (i.e., 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	1 year
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), 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 (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

- Abstral
- Actiq
- fentanyl citrate
- Fentora
- Lazanda nasal spray, non-aerosol 100 mcg/spray, 300 mcg/spray, 400 mcg/spray
- Subsys sublingual spray, non-aerosol 100 mcg/spray, 200 mcg/spray, 400 mcg/spray, 600 mcg/spray, 800 mcg/spray

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	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.

TRELEGY

Products Affected

- Trelegy Ellipta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	diagnosis, medication history
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Approve only if the patient has tried a single-entity LAMA AND fixed-dose combination LAMA/LABA in the past, unless the patient meets one of the following criteria: 1) Patient is currently receiving a fixed-dose LAMA/LABA combination product, OR 2) Patient currently receiving a LAMA + a LABA as two single-entity inhalers, OR 3) Patients currently receiving a fixed-dose ICS/LABA or an ICS + a LABA as two single-entity inhalers, patient must try a LAMA but does not need to try a fixed-dose LAMA/LABA combination product, OR 4) Patient current receiving an ICS, LAMA, and LABA (all three chemical classes in any combination of single-entity or combination products).

TREMFYA

Products Affected

- Tremfya

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tremfya for a covered use.
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Previous medication use
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial therapy - 3 months, Continuation therapy - 3 years
Other Criteria	Initial Therapy - Approve if the patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, or Cosentyx. Continuation Therapy - Patient must have responded, as determined by the prescriber.

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 exemestane. 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 [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

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, 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, 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 Small Lymphocytic Lymphoma (SLL). Plus Mantle Cell Lymphoma. 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. SLL-approve if the patient has tried one prior therapy. Mantle Cell Lymphoma-approve if the patient has tried one prior therapy.

VERZENIO

Products Affected

- Verzenio

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 - 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 in patients who have not had disease progression while on Kisqali, Ibrance or Verzenio when the pt meets ONE of the following 1. Pt is postmenopausal and Verzenio 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 GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Verzenio will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole 3. Patient is postmenopausal and meets the following conditions: The patient has relapsed or progressed during prior endocrine therapy with at least one of the following: anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol AND Verzenio will be used in combination with Faslodex. 4. patient is premenopausal or perimenopausal and meets the following conditions: The patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND patient has relapsed or progressed during prior endocrine therapy

PA Criteria	Criteria Details
	<p>with at least one of the following: anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol AND Verzenio will be used in combination with Faslodex 5. patient is postmenopausal, premenopausal, perimenopausal or 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) and meets the following conditions: Verzenio will be used as monotherapy AND patient's breast cancer has relapsed or progressed during prior endocrine therapy with at least one of the following: anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol AND patient has tried chemotherapy for metastatic breast cancer. 6. pt is a man who is receiving GnRH agonist AND Verzenio with be used as first line endocrine therapy in combination with anastrozole, exemestane, tamoxifen or letrozole.</p>

VIEKIRA

Products Affected

- Viekira Pak
- Viekira XR

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Viekira/Viekira XR for a covered use
Exclusion Criteria	Previous failure of Viekira/Viekira XR or Technivie in patients with minimal liver disease. Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	Genotype 1, Cirrhosis status and genotype 1 subtype
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a 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. And, patients with genotype 1 must have a trial with Harvoni or Epclusa prior to approval of Viekira/Viekira XR, unless Harvoni and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines.

VOSEVI

Products Affected

- Vosevi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Vosevi for a Covered Use.
Exclusion Criteria	N/A
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 consistent with current AASLD/IDSA guidance.

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, 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 recurrent, advanced or metastatic disease. Advanced RCC - approve. 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 and/or surgery. GIST - approve if the patient has tried TWO of the following: Gleevec, Sutent, or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq).

XALKORI

Products Affected

- Xalkori

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.

XELJANZ

Products Affected

- Xeljanz oral tablet 5 mg
- Xeljanz XR

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Xeljanz/XR for a Covered Use.
Exclusion Criteria	Concurrent use with a biologic for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	N/A
Prescriber Restrictions	RA, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist.
Coverage Duration	Authorization will be for 3 months initial, 3 years cont.
Other Criteria	RA/PsA 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). Continuation Therapy - Patient must have responded, as determined by the prescriber.

XENAZINE

Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg
- Xenazine oral tablet 12.5 mg, 25 mg

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	If the brand is requested the patient must have tried and cannot take generic tetrabenazine tablets as identified by the prescribing physician.

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]) 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	Concurrent use with an Interleukin (IL) Antagonist Monoclonal Antibody
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

PA Criteria	Criteria Details
	<p>(LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2) inadequate control demonstrated by 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.</p>

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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

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, dexamethylphenidate, dextroamphetamine), modafinil, or Nuvigil.

YONSA

Products Affected

- Yonsa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Yonsa for a covered use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concomitant medications
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Metastatic castration-resistant prostate cancer (mCRPC) - approve if the patient will be using Yonsa in combination with methylprednisolone.

ZARXIO

Products Affected

- Zarxio

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	Under CMS Review
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 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,

PA Criteria	Criteria Details
	<p>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), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, Neulasta, Neupogen) 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).</p>

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	N/A
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 have unresctable, advanced or metastatic melanoma. HCL - must have relapsed or refractory disease AND tried at least two therapies for hairy cell leukemia. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy.

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. And, patients with genotype 1 and genotype 4 must have a trial with Harvoni or Epclusa prior to approval of Zepatier, unless Harvoni and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines.

ZYDELIG

Products Affected

- Zydelig

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus Marginal Zone Lymphoma.
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-approve if the patient has tried one prior therapy. Marginal Zone Lymphoma/Follicular B-Cell Non-Hodgkin Lymphoma/SLL - approve if the patient has tried two prior therapies.

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 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 as detected by an approved test or ROS1 Rearrangement. 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 Prostate Cancer-Regional Risk Group or Locally Advanced. Plus Prostate Cancer - Metastatic (Castration-Resistant or Castration-Sensitive), Post-External Beam Radiation Therapy (EBRT). 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	Prostate Cancer-Metastatic, Castration-Resistant (mCRPC) and Metastatic, Castration-Sensitive (mCSPC), high risk-Approve if Zytiga is being used in combination with prednisone. Prostate Cancer - Regional Risk Group or Locally Advanced. Approve if the patient meets all of the following criteria (A, B, and C): A) Zytiga is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii): i. Zytiga with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant]) OR ii. Patient has had an orchiectomy. Prostate Cancer - Metastatic (Castration-Resistant or Castration-Sensitive), Post-External Beam Radiation Therapy (EBRT)-Approve if the patient meets all of the following criteria (A, B, C, D, and E): A) Zytiga is used in combination with prednisone AND B) Patient meets one of the following criteria (i, ii, or iii): i. Zytiga with prednisone is

PA Criteria	Criteria Details
	<p>used in combination with gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant]) OR ii. Zytiga with prednisone is used in combination with GnRH antagonist (e.g., Firmagon [degarelix for injection]) OR iii. Patient has had an orchiectomy. C) Patient meets one of the following criteria (i or ii): i. There is an increase in prostate specific antigen (PSA) after EBRT OR ii Patient has had a positive digital rectal exam (DRE) after EBRT AND D) Patient is not a candidate for local therapy AND E) Patient has had a positive bone scan.</p>

PART B VERSUS PART D

Products Affected

- Abelcet
- acetylcysteine
- Actimmune
- acyclovir sodium intravenous solution
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 mL, 1.25 mg/3 mL, 2.5 mg /3 mL (0.083 %), 5 mg/mL
- AmBisome
- 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 %
- amphotericin B
- aprepitant
- Astagraf XL
- Azasan
- azathioprine
- Bethkis
- Brovana
- budesonide inhalation
- Cancidas
- caspofungin
- CellCept
- Cesamet
- Clinimix 5%/D15W Sulfite Free
- Clinimix 5%/D25W sulfite-free
- Clinimix 2.75%/D5W Sulfite Free
- Clinimix 4.25%/D10W Sulf Free
- Clinimix 4.25%/D5W Sulfite Free
- Clinimix 4.25%-D20W sulf-free
- Clinimix 4.25%-D25W sulf-free
- Clinimix 5%-D20W(sulfite-free)
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- Clinimix E 2.75%/D5W Sulf Free
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- Clinimix E 4.25%/D25W Sul Free
- Clinimix E 4.25%/D5W Sulf Free
- Clinimix E 5%/D15W Sulfite Free
- Clinimix E 5%/D20W Sulfite Free
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- Clinisol SF 15 %
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- Engerix-B Pediatric (PF) intramuscular syringe
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- Firmagon kit w diluent syringe
- Freamine HBC 6.9 %
- Gengraf oral capsule 100 mg, 25 mg
- Gengraf oral solution
- granisetron HCl oral
- Hepatamine 8%
- Imuran
- Intralipid intravenous emulsion 20 %
- Intralipid intravenous emulsion 30 %
- Intron A injection
- ipratropium bromide inhalation
- ipratropium-albuterol
- levalbuterol HCl
- Marinol
- Medrol
- methotrexate sodium
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- mycophenolate mofetil
- mycophenolate sodium
- Myfortic
- Nebupent
- Neoral
- Nephramine 5.4 %
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- ondansetron

- ondansetron HCl oral
- Orapred ODT
- Perforomist
- Plenamine
- prednisolone sodium phosphate oral tablet, disintegrating
- Prednisone Intensol
- prednisone oral tablet
- Premasol 10 %
- Premasol 6 %
- Procalamine 3%
- Prograf oral
- Prosol 20 %
- Pulmicort
- Pulmozyme
- Rapamune
- Rayos
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL
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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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