ACTEMRA

Products Affected

- Actemra intravenous

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried
Age Restrictions	N/A
Prescriber Restrictions	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy).
Coverage Duration	1 year
Other Criteria	RA initial - approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz], Orencia, Rinvoq or Xeljanz/XR (Note: if the patient does not meet this requirement, previous trial(s) with the following drugs will be counted towards meeting the try TWO requirement: Cimzia, infliximab, golimumab SC/IV, Amjevita (NDCs starting with 72511-) or another non-preferred adalimumab product will also count. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product., OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial-approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, Orencia, Xeljanz or an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz]. (Note: if the patient does not meet this requirement, a previous trial with the drug infliximab or a non-preferred adalimumab product will be counted towards meeting the try TWO requirement. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product), OR B) patient has heart failure or a previously

PA Criteria	Criteria Details
	treated lymphoproliferative disorder. Cont tx, RA/PJIA- approve if the pt had a response as determined by the prescriber. Interstitial lung disease associated with systemic sclerosis initial-approve if the patient has elevated acute phase reactants AND the diagnosis is confirmed by high-resolution computed tomography. Interstitial lung disease assoc with systemic sclerosis, Cont tx-approve if the patient had adequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ACTEMRA SQ

Products Affected

- Actemra ACTPen
- Actemra subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	Interstitial lung disease-18 years and older (initial and continuation)
Prescriber Restrictions	RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
Coverage Duration	1 year
Other Criteria	RA initial - approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz], Orencia, Rinvoq or Xeljanz/XR (Note: if the patient does not meet this requirement, previous trial(s) with the following drugs will be counted towards meeting the try TWO requirement: Cimzia, infliximab, golimumab SC/IV, Amjevita (NDCs starting with 72511-) or another non-preferred adalimumab product will also count. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product., OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial-approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, Orencia, Xeljanz or an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz]. (Note: if the patient does not meet this requirement, a previous trial with the drug infliximab or a non-preferred adalimumab product will be counted towards meeting the try TWO requirement. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product), OR B) patient has heart failure or a previously

PA Criteria	Criteria Details
	treated lymphoproliferative disorder. Cont tx, RA/PJIA - approve if the pt had a response as determined by the prescriber. Interstitial lung disease associated with systemic sclerosis initial-approve if the patient has elevated acute phase reactants AND the diagnosis is confirmed by high-resolution computed tomography. Interstitial lung disease assoc with systemic sclerosis, Cont tx-approve if the patient had adequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ACYCLOVIR (TOPICAL)

Products Affected

- acyclovir topical ointment

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADALIMUMAB OTHER

Products Affected

- adalimumab-adaz
- Cyltezo(CF) Pen
- Cyltezo(CF) Pen Crohn's-UC-HS
- Cyltezo(CF) Pen Psoriasis-UV
- Cyltezo(CF) subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL
- Hyrimoz CF (ONLY NDCS STARTING WITH 61314) subcutaneous pen injector 40 mg/0.4 mL, 80 mg/0.8 mL
- Hyrimoz CF (ONLY NDCS STARTING WITH 61314) subcutaneous syringe 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL
- Hyrimoz Pen Crohn's-UC Starter
- Hyrimoz Pen Psoriasis Starter
- Hyrimoz(CF) Pedi Crohn Starter subcutaneous syringe 80 mg/0.8 mL, 80 mg/0.8 mL- 40 mg/0.4 mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried
Age Restrictions	CD, 6 or older (initial). UC, 5 or older (initial). PP-18 years and older (initial)
Prescriber Restrictions	Init tx only-RA/JIA/JRA/Ankylosing spondylitis, prescr/consult w/rheum. PsA, prescr/consult w/rheum or derm. PP, prescr/consult w/derm. UC/ CD, prescr/consult w/gastro. HS, presc/consult w/derm. UV, prescr/consult w/ophthalmologist.
Coverage Duration	1 year
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 one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (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. Plaque psoriasis (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

PA Criteria	Criteria Details
	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. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). cont tx - must respond to tx as determined by prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADBRY

Products Affected

- Adbry

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
Coverage Duration	Initial-Atopic Dermatitis-4 months, Continuation-1 year
Other Criteria	Atopic Dermatitis, initial-patient has atopic dermatitis involvement estimated to be greater than or equal to 10 percent of the body surface area and patient meets a and b: a. Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid AND b. Inadequate efficacy was demonstrated with the previously tried topical corticosteroid therapy.Continuation- Approve if the patient has been receiving Adbry for at least 4 months and patient has responded to therapy. Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Adbry should be considered under initial therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADEMPAS

Products Affected

- Adempas

PA Criteria	Criteria Details
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	1 year
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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADSTILADRIN

Products Affected

- Adstiladrin

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a urologist or an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Non-Muscle Invasive Bladder Cancer, approve if the patient meets all of the following (A, B and C): A) patient has high-risk, Bacillus Calmette-Guerin (BCG)-unresponsive disease, and B) the patient has carcinoma in situ (CIS) with or without high-grade papillary Ta/T1 tumors OR the patient has high-grade papillary Ta/T1 tumors without CIS, and C) the medication is used for initial treatment OR the medication is used for cytology- and bladder-biopsy positive, imaging- and cystoscopy-negative, recurrent or persistent disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AIMOVIG

Products Affected

- Aimovig Autoinjector

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Ajovy, Vyepti or Emgality
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 one standard prophylactic pharmacologic therapy (e.g., anticonvulsant, beta-blocker), and has had inadequate response or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try a standard prophylactic pharmacologic therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALDURAZYME

Products Affected

- Aldurazyme

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient alpha-L-iduronidase activity in leukocytes, fibroblasts, plasma, or serum OR has a molecular genetic test demonstrating alpha-L-iduronidase gene mutation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALECENSA

Products Affected

- Alecensa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Non-small cell lung cancer-approve if the patient has metastatic disease and anaplastic lymphoma kinase (ALK)-positive non-small cell lung disease. Anaplastic large cell lymphoma-approve if the patient has ALK-positive disease. Erdheim-Chester disease-approve if the patient has ALK rearrangement/fusion-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anaplastic large cell lymphoma, Erdheim Chester disease
Part B Prerequisite	No

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- Prolastin-C

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Alpha1-Antitrypsin Deficiency with Emphysema (or Chronic Obstructive Pulmonary Disease)-approve if the patient has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALUNBRIG

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	ALK status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has IMT with ALK translocation. Metastatic NSCLC, must be ALK-positive, as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT)
Part B Prerequisite	No

AMJEVITA

Products Affected

- Amjevita (Only NDCs starting with 55513) subcutaneous auto-injector 40 mg/0.8 mL
- Amjevita (Only NDCs starting with 55513) subcutaneous syringe 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL

PA Criteria	Criteria Details
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 (initial therapy only). Ulcerative colitis (UC), 5 or older (initial therapy only). PP-18 years and older (initial therapy only).
Prescriber Restrictions	RA/JIA/JRA/Ankylosing spondylitis, prescribed/consult w/rheumatologist (initial therapy only). Psoriatic arthritis (PsA), prescribed/consult w/a rheumatologist or dermatologist (initial therapy only). Plaque psoriasis (PP), prescribed/consult w/a dermatologist (initial therapy only). UC/ CD, prescribed/consult w/gastroenterologist (initial therapy only). HS, prescr/consult w/dermatologist (initial therapy only). UV, presc/consult w/ophthalmologist (initial therapy only).
Coverage Duration	1 year
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 one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (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. Plaque psoriasis (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

PA Criteria	Criteria Details
	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 conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). FDA approve indications cont tx - must respond to tx as determined by prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ANTIBIOTICS (IV)

Products Affected

- amikacin injection solution 1,000 mg/4 mL, 500 mg/2 mL
- ampicillin sodium
- ampicillin-sulbactam
- azithromycin intravenous
- aztreonam
- Bicillin C-R
- Bicillin L-A
- cefoxitin
- cefoxitin in dextrose, iso-osm
- ceftazidime
- cefuroxime sodium injection recon soln 750 mg
- cefuroxime sodium intravenous
- ciprofloxacin in 5 % dextrose
- clindamycin in 5 % dextrose
- clindamycin phosphate injection
- clindamycin phosphate intravenous
- colistin (colistimethate Na)
- Doxy-100
- doxycycline hyclate intravenous
- ertapenem
- gentamicin in NaCl (iso-osm) intravenous piggyback 100 mg/100 mL, 60 mg/50 mL, 80 mg/100 mL, 80 mg/50 mL
- gentamicin injection solution 40 mg/mL
- gentamicin sulfate (ped) (PF)
- imipenem-cilastatin
- levofloxacin in D5W
- levofloxacin intravenous
- lincomycin
- linezolid in dextrose 5%
- linezolid-0.9% sodium chloride
- meropenem intravenous recon soln 1 gram, 500 mg
- Metro I.V.
- metronidazole in NaCl (iso-os)
- moxifloxacin-sod.chloride(iso)
- nafcillin in dextrose iso-osm
- nafcillin injection
- nafcillin intravenous recon soln 2 gram
- oxacillin in dextrose(iso-osm)
- oxacillin injection
- penicillin G pot in dextrose
- penicillin G potassium
- penicillin G sodium
- Pfizerpen-G
- streptomycin
- sulfamethoxazole-trimethoprim intravenous
- Tazicef
- Teflaro
- tigecycline
- tobramycin sulfate injection recon soln
- tobramycin sulfate injection solution
- vancomycin in 0.9 % sodium chl intravenous piggyback 1 gram/200 mL, 500 mg/100 mL, 750 mg/150 mL
- vancomycin injection
- vancomycin intravenous recon soln 1,000 mg, 10 gram, 5 gram, 500 mg, 750 mg
- Vibativ intravenous recon soln 750 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis

PA Criteria	Criteria Details
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ANTIFUNGALS (IV)

Products Affected

- Cresemba
- fluconazole in NaCl (iso-osm)
- voriconazole

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

APOKYN

Products Affected

- APOKYN
- apomorphine

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a serotonin 5-HT3 Antagonist
Required Medical Information	Diagnosis, other therapies
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's disease (PD), new to therapy-approve if the patient meets the following criteria: 1. Patient has advanced PD, 2. patient is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, 3. Patient is currently receiving carbidopa/levodopa. Parkinson's disease (PD), patients currently receiving apokyn or apomorphine-approve if the patient meets the following criteria: 1. patient has advanced PD, 2. patient is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, 3. patient is currently receiving carbidopa/levodopa and 4.patient has previously tried one other treatment for off episodes and had significant intolerance or inadequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ARCALYST

Products Affected

- Arcalyst

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent biologic therapy
Required Medical Information	N/A
Age Restrictions	Initial tx CAPS/Pericarditis-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. DIRA initial-rheum, geneticist, derm, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum
Coverage Duration	CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont
Other Criteria	CAPS renewal - approve if the patient has had a response as determined by the prescriber. DIRA initial-approve if the patient weighs at least 10 kg, genetic test confirms a mutation in the IL1RN gene and the patient has demonstrated a clinical benefit with anakinra subcutaneous injection. DIRA cont-approve if the patient has responded to therapy. Pericarditis initial-approve if the patient has recurrent pericarditis AND for the current episode, the patient is receiving standard treatment or standard treatment is contraindicated. Continuation-approve if the patient has had a clinical response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ARIKAYCE

Products Affected

- Arikayce

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous medication history
Age Restrictions	MAC-18 years and older (initial therapy)
Prescriber Restrictions	MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections. Cystic fibrosis-prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis
Coverage Duration	Initial-1 year Cont, negative culture approve up to 1yr total, positive culture-1 year
Other Criteria	MAC Lung disease, initial-approve if the patient has a positive sputum culture for mycobacterium avium complex and the culture was collected within the past 3 months and was collected after the patient has completed a background multidrug regimen, the Mycobacterium avium complex isolate is susceptible to amikacin with a minimum inhibitor concentration (MIC) of less than or equal to 64 microgram/mL AND Arikayce will be used in conjunction to a background multidrug regimen. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin). MAC Lung Disease, continuation-approve if Arikayce will be used in conjunction with a background multidrug regimen AND i. Patient meets ONE of the following criteria (a or b):a)patient has not achieved negative sputum cultures for Mycobacterium avium complex OR b) patient has achieved negative sputum cultures for Mycobacterium avium complex for less than 12 months. Cystic fibrosis-patient has pseudomonas aeruginosa in culture of the airway.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Cystic fibrosis pseudomonas aeruginosa infection

PA Criteria	Criteria Details
Part B Prerequisite	No

ASPARLAS

Products Affected

- Asparlas

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 month to 21 years
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AUBAGIO

Products Affected

- Aubagio
- teriflunomide

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of teriflunomide with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of MS, to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
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	Initial treatment - approve if the patient has tried generic dimethyl fumarate. Note: Prior use of brand Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. Cont tx - approve if the patient has been established on teriflunomide.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AVONEX

Products Affected

- Avonex intramuscular pen injector kit
- Avonex intramuscular syringe kit

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year
Other Criteria	Cont tx-approve if the patient has been established on Avonex.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AYVAKIT

Products Affected

- Ayvakit

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation or if the patient has tried two of the following: Gleevec (imatinib), Sutent (sunitinib), Sprycel (dasatinib), Stivarga (regorafenib) or Qinlock (ripretinib). Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for PDGFRA D842V mutation. Systemic mastocytosis-Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has either indolent systemic mastocytosis or one of the following subtypes of advanced systemic mastocytosis-aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm or mast cell leukemia.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid neoplasms with Eosinophilia
Part B Prerequisite	No

BALVERSA

Products Affected

- Balversa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies, test results
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy or checkpoint inhibitor therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BENLYSTA

Products Affected

- Benlysta

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or Lupkynis
Required Medical Information	Diagnosis, medications that will be used in combination, autoantibody status
Age Restrictions	18 years and older (initial).
Prescriber Restrictions	SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)
Coverage Duration	SLE-Initial-4 months, cont-1 year. Lupus Nephritis-6 mo initial, 1 year cont
Other Criteria	Lupus Nephritis Initial-approve. Cont-approve if the patient has responded to the requested medication. SLE-Initial-The patient has autoantibody-positive SLE, defined as 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. 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

BESREMI

Products Affected

- Besremi

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other interferon products
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BETASERON/EXTAVIA

Products Affected

- Betaseron subcutaneous kit

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year
Other Criteria	For patients requesting Betaseron-Cont tx-approve if the patient has been established on Betaseron.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BEVACIZUMAB

Products Affected

- Mvasi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Intracranial and spinal ependymoma-18 years and older
Prescriber Restrictions	All diagnoses except Neovascular or vascular ophthalmic conditions-Prescribed by or in consultation with an oncologist
Coverage Duration	Neovascular or vascular ophthalmic conditions - 3 years, all others-1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. Patients new to therapy, requesting Alymsys, Avastin or Mvasi must have a trial of Zirabev and cannot continue to use the preferred product due to a formulation difference in the inactive ingredient(s) [e.g., differences in the stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction prior to approval. Patients with a diagnosis of neovascular or vascular ophthalmic conditions are not required to have a trial of Zirabev prior to approval.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Endometrial carcinoma, mesothelioma, neovascular or vascular ophthalmic conditions, small bowel adenocarcinoma, soft tissue sarcoma, vulvar cancer (squamous cell carcinoma), anaplastic gliomas, intracranial and spinal ependymoma (excluding subependymoma), meningiomas
Part B Prerequisite	No

BEXAROTENE (ORAL)

Products Affected

- bexarotene

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BONIVA INJECTION

Products Affected

- ibandronate intravenous

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other medications for Osteoporosis
Required Medical Information	Diagnosis, test results
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Treatment of postmenopausal osteoporosis, must meet ONE of the following 1. T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, or total hip, 2. has had osteoporotic fracture or fragility fracture, 3. had a T-score (current or at any time in the past) between 1.0 and -2.5 at the lumbar spine, femoral neck, or total hip and the physician determines the patient is at high risk for fracture AND has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of bone mineral density (BMD), lack of BMD increase), had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy, or experienced intolerability to an oral bisphosphonate (e.g., severe GI-related adverse effects) 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 the patient has had an osteoporotic fracture or a fragility fracture.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No

BOSENTAN/AMBRISENTAN

Products Affected

- ambrisentan
- bosentan

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath
Age Restrictions	N/A
Prescriber Restrictions	For treatment of pulmonary arterial hypertension, ambrisentan or bosentan 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 1 year.
Other Criteria	CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan)
Part B Prerequisite	No

BOSULIF

Products Affected

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

PA Criteria	Criteria Details
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	18 years and older
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).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia
Part B Prerequisite	No

BOTOX

Products Affected

- Botox

PA Criteria	Criteria Details
Exclusion Criteria	Use in the management of cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platsymal bands, rejuvenation of the peri-orbital region)
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Migraine headache prevention-prescribed by, or after consultation with, a neurologist or HA specialist.
Coverage Duration	Authorization will be for 12 months
Other Criteria	Blepharospasm Associated with Dystonia or Strabismus-approve, Cervical Dystonia-approve, Hyperhidrosis, primary axillary-approve, Chronic low back pain after trial with at least 2 other pharmacologic therapies (eg, NSAID, antispasmodics, muscle relaxants, opioids, antidepressants) and if being used as part of a multimodal therapeutic pain management program. Essential tremor after a trial with at least 1 other pharmacologic therapy (eg, primidone, propranolol, benzodiazepines, gabapentin, topiramate), Migraine Headache Prevention-must have 15 or more migraine headache days per month with headache lasting 4 hours per day or longer (prior to initiation of Botox therapy) AND have tried at least two standard prophylactic pharmacologic therapies, each from a different pharmacologic class (e.g., beta-blocker, anticonvulsant, tricyclic antidepressant) and patient has had inadequate efficacy or adverse events. If the patient is currently taking Botox for migraine headache prevention, patient must have had significant clinical benefit. Overactive bladder with symptoms of urge urinary incontinence, urgency and frequency-approve if the patient has tried at least one other pharmacologic therapy. Spasticity, limb-approve. Urinary incontinence associated with a neurological condition-approve if the patient has tried at least one other pharmacologic therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Achalasia, Anal Fissure, Chronic facial pain/pain associated with TMJ dysfunction, Chronic low back pain, Dystonia, other than cervical, Essential tremor, Hyperhidrosis, gustatory, hyperhidrosis, Palmar/Plantar and facial, Myofascial pain, Ophthalmic disorders, other than blepharospasm or Strabismus, Sialorrhea, chronic, Spasticity, other than limb (i.e., due to cerebral palsy, stroke, brain injury, spinal cord injury, MS, hemifacial spasm)
Part B Prerequisite	No

BRAFTOVI

Products Affected

- Braftovi oral capsule 75 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. Colon or Rectal cancer- approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer. NSCLC- approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BRIUMVI

Products Affected

- Briumvi

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of MS, to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS.
Coverage Duration	1 year
Other Criteria	Continuation-approve if the patient has experienced a beneficial clinical response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BRUKINSA

Products Affected

- Brukinsa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Mantle Cell Lymphoma - approve if the patient has tried at least one systemic regimen or patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail). Chronic lymphocytic leukemia/small lymphocytic lymphoma-approve. Marginal zone lymphoma-approve if the patient has tried at least one systemic regimen. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

C1 ESTERASE INHIBITORS

Products Affected

- Cinryze

PA Criteria	Criteria Details
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	1 year
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II], Prophylaxis, Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50 percent of normal) at baseline and lower than normal serum C4 levels at baseline. Patient is currently taking Cinryze for prophylaxis - approve if the patient meets the following criteria (i and ii): i) patient has a diagnosis of HAE type I or II, and ii) according to the prescriber, the patient has had a favorable clinical response since initiating Cinryze as prophylactic therapy compared with baseline.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CABLIVI

Products Affected

- Cablivi injection kit

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concurrent medications
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	Approve for 12 months
Other Criteria	aTTP-approve if the requested medication was initiated in the inpatient setting in combination with plasma exchange therapy AND patient is currently receiving at least one immunosuppressive therapy AND if the patient has previously received Cablivi, he/she has not had more than two recurrences of aTTP while on Cablivi.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CABOMETYX

Products Affected

- Cabometyx

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, histology, RET gene rearrangement status
Age Restrictions	Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried a vascular endothelial growth factor receptor (VEGFR)-targeted therapy. Endometrial carcinoma-approve if the patient has tried one systemic regimen. GIST-approve if the patient has tried two of the following-imatinib, Ayvakit, sunitinib, dasatinib, Stivarga or Qinlock. NSCLC-approve if the patient has RET rearrangement positive tumor.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Non-Small Cell Lung Cancer, Gastrointestinal stromal tumors (GIST), Bone cancer, Endometrial Carcinoma
Part B Prerequisite	No

CALQUENCE

Products Affected

- Calquence
- Calquence (acalabrutinib mal)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma.
Part B Prerequisite	No

CAPRELSA

Products Affected

- Caprelsa oral tablet 100 mg, 300 mg

PA Criteria	Criteria Details
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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Non-Small Cell Lung Cancer with RET Gene Rearrangements
Part B Prerequisite	No

CARBAGLU

Products Affected

- carglumic acid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	NAGS-Pt meets criteria no genetic test - 3mo. Pt had genetic test - 12mo, other-approve 7 days
Other Criteria	N-Acetylglutamate synthase deficiency with hyperammonemia-Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency or if the patient has hyperammonemia. Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia, Acute Treatment-approve if the patient's plasma ammonia level is greater then or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (generic carglumic acid)
Part B Prerequisite	No

CAYSTON

Products Affected

- Cayston

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.
Coverage Duration	1 year
Other Criteria	Approve if the patient has Pseudomonas aeruginosa in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CEPROTIN

Products Affected

- Ceprotin (Blue Bar)
- Ceprotin (Green Bar)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Protein C Deficiency, Severe-approve if the patient meets the following criteria A, B and C: A) The diagnosis of protein C deficiency is confirmed by at least one of the following (i, ii, or iii): i. Plasma protein C activity below the lower limit of normal based on the age-specific reference range for the reporting laboratory OR ii. Plasma protein C antigen below the lower limit of normal based on the age-specific reference range for the reporting laboratory OR iii. Genetic testing demonstrating biallelic mutations in the PROC gene AND B) Acquired causes of protein C deficiency have been excluded AND C) Patient has a current or prior history of symptoms associated with severe protein C deficiency (e.g., purpura fulminans, thromboembolism).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CHEMET

Products Affected

- Chemet

PA Criteria	Criteria Details
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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CHENODAL

Products Affected

- Chenodal

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	For the treatment of gallstones, approve if the patient has tried or is currently using an ursodiol product.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CHOLBAM

Products Affected

- Cholbam oral capsule 250 mg, 50 mg

PA Criteria	Criteria Details
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 or molecular genetic testing consistent with the diagnosis. 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 or molecular genetic testing consistent with the diagnosis 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CIBINQO

Products Affected

- Cibinqo

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD). Concurrent use with an Anti-Interleukin Monoclonal Antibody. Concurrent use with other Janus Kinase Inhibitors. Concurrent use with Xolair (omalizumab subcutaneous injection). Concurrent use with other potent immunosuppressants.
Required Medical Information	Diagnosis
Age Restrictions	AD-12 years of age and older (initial therapy)
Prescriber Restrictions	Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
Coverage Duration	Initial-Atopic Dermatitis-3 months, Continuation-1 year
Other Criteria	Atopic Dermatitis, initial-approve if the patient has had a 3-month trial of at least one traditional systemic therapy OR patient has tried at least one traditional systemic therapy but was unable to tolerate a 3-month trial. Note: Examples of traditional systemic therapies include methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis. Continuation-Approve if the patient has been receiving Cibinqo for at least 90 days AND patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Cibinqo) in at least one of the following: estimated body surface area affected, erythema, induration/papulation/edema, excoriations, lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis AND compared with baseline (prior to receiving Cibinqo), patient experienced an improvement in at least one symptom, such as decreased itching. Note: A patient who has received less than 3 months of therapy or who is restarting therapy with Cibinqo should be considered under initial therapy.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CIMERLI

Products Affected

- Cimerli

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Administered by or under the supervision of an ophthalmologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Retinopathy of prematurity
Part B Prerequisite	No

CIMZIA

Products Affected

- Cimzia
- Cimzia Powder for Reconst
- Cimzia Starter Kit

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried
Age Restrictions	18 years and older for CD and PP (initial therapy).
Prescriber Restrictions	All dx initial therapy only. 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. PP, prescribed by or in consultation with a dermatologist. nr-axSpA-prescribed by or in consultation with a rheumatologist
Coverage Duration	1 year
Other Criteria	AS initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz], Xeljanz/XR, Taltz. Note: if the patient does not meet this requirement, a previous trial of Amjevita (NDCs starting with 72511) or another non-preferred adalimumab product will also count. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product. PsA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz], Taltz, Stelara, Otezla, Orencia, Rinvoq, Skyrizi or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of Amjevita (NDCs starting with 72511) or another non-preferred adalimumab product will also count. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product.RA initial tx, approve if the patient has tried two of the following drugs in the past: Enbrel, an adalimumab product [i.e.,

PA Criteria	Criteria Details
	Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz], Orencia, Rinvoq or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of Amjevita (NDCs starting with 72511) or another non-preferred adalimumab product will also count. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product. CD initial tx, approve if patient has previously tried an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz or Amjevita (NDCs starting with 55513-)]. Note: if the patient does not meet this requirement, a previous trial of Amjevita (NDCs starting with 72511) or any other non-preferred adalimumab product will also count. Plaque Psoriasis (PP), initial tx-approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz], Skyrizi, Stelara SC, Otezla, or Taltz. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz counts as ONE Preferred Product. Cont tx, AS/PsA/RA/CD/PP - approve if the pt had a response as determined by the prescriber. Non-radiographic axial spondylitis (nr-axSpA), initial tx-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroilitis reported on MRI. nr-axSpA continuation tx-approve if the patient has had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CLOBAZAM

Products Affected

- clobazam oral suspension
- clobazam oral tablet
- Sympazan

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other medications tried
Age Restrictions	2 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Lennox-Gastaut Syndrome, initial therapy-patient has tried one of the following: lamotrigine, topiramate, rufinamide, felbamate, or Epidiolex. Treatment refractory seizures/epilepsy, initial therapy-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Continuation-prescriber confirms patient is responding to therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Dravet Syndrome and treatment-refractory seizures/epilepsy
Part B Prerequisite	No

CLOMIPHENE

Products Affected

- Clomid
- clomiphene citrate

PA Criteria	Criteria Details
Exclusion Criteria	Use in patients for infertility
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Woman (a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Male hypogonadism
Part B Prerequisite	No

COLUMVI

Products Affected

- Columvi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-cell lymphoma-approve if the patient has received two or more lines of systemic therapy, the medication will be given as a single agent and the patient has or will receive pretreatment with obinutuzmab intravenous infusion before the first dose of Columvi. Note: Examples of diffuse large B-cell lymphoma (DLBCL) include DLBCL not otherwise specified, high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma or nodal marginal zone lymphoma. Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and DHA (dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin) +/- rituximab. Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma-approve if the patient has received two or more lines of systemic therapy, the medication will be given as a single agent and the patient has or will receive pretreatment with obinutuzmab intravenous infusion before the first dose of Columvi. Note: HIV-related B-cell lymphomas includes HIV-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus-8 (HHV8) positive DLBCL. Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and R-EPOCH (rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin). Post-transplant lymphoproliferative disorders- approve if the

PA Criteria	Criteria Details
	patient has received two or more lines of systemic therapy, the medication will be given as a single agent and the patient has or will receive pretreatment with obinutuzmab intravenous infusion before the first dose of Columvi. Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma.Post-transplant lymphoproliferative disorders.
Part B Prerequisite	No

COMETRIQ

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis.
Age Restrictions	NSCLC/MTC-18 years and older, DTC-12 years and older
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 and patient has tried a Vascular Endothelial Growth Factor Receptor (VEGFR)-targeted therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma
Part B Prerequisite	No

COPIKTRA

Products Affected

- Copiktra

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	T-cell lymphoma-For peripheral T-cell lymphoma, approve. For breast implant-associated anaplastic large cell lymphoma, or hepatosplenic T-cell lymphoma, approve if the patient has relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	T-cell Lymphoma
Part B Prerequisite	No

COTELLIC

Products Affected

- Cotellic

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Melanoma initial - must have BRAF V600 mutation.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf. CNS Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i) Adjuvant treatment of pilocytic astrocytoma or pleomorphic xanthoastrocytoma or ganglioglioma, OR ii) recurrent disease for low-grade glioma or anaplastic glioma or glioblastoma, OR iii) melanoma with brain metastases AND medication will be taken in combination with Zelboraf (vemurafenib tablets). Histiocytic Neoplasm-approve if the patient meets one of the following (i, ii, or iii): i) patient has Langerhans cell histiocytosis and one of the following: multisystem disease or pulmonary disease or central nervous system lesions, OR ii) patient has Erdheim Chester disease, OR iii) patient has Rosai-Dorfman disease AND patient has BRAF V600 mutation-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Cancer, Histiocytic Neoplasm
Part B Prerequisite	No

CRESEMBA (ORAL)

Products Affected

- Cresemba

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Candidiasis of the esophagus - HIV infection, sepsis
Part B Prerequisite	No

CRYSVITA

Products Affected

- Crysvita

PA Criteria	Criteria Details
Exclusion Criteria	Chronic Kidney Disease (CKD), Severe Renal Impairment or End Stage Renal Disease
Required Medical Information	Diagnosis, lab values
Age Restrictions	TIO-2 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or nephrologist (initial therapy)
Coverage Duration	XLH-1 year (initial/cont), TIO-initial-6 months, cont-1 year
Other Criteria	XLH-Initial therapy-Approve if the patient has had a baseline (prior to any XLH treatment) serum phosphorus level that was below the normal range for age and patient meets ONE of the following (a or b): a) The patient has had a baseline (i.e., prior to any XLH treatment tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender OR b) The patient has had a genetic test confirming the diagnosis of X-linked hypophosphatemia via identification of a PHEX mutation AND if the patient is greater than or equal to 18 years of age, the patient is currently exhibiting one or more signs or symptoms of XLH. Continuation-approve if the patient is continuing to derive benefit as determined by the prescribing physician. TIO-approve if the patient has a mesenchymal tumor that cannot be curatively resected or identified/localized AND the patient is currently exhibiting one or more signs or symptoms of TIO AND patient has had a baseline (prior to any TIO treatment) serum phosphorus level that was below the normal range for age AND patient has had a baseline (prior to any TIO treatment) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender. Cont-approve if the patient is continuing to derive benefit as determined by the prescribing physician.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No

CYSTEAMINE (OPHTHALMIC)

Products Affected

- Cystaran

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases
Coverage Duration	1 year
Other Criteria	Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CYSTEAMINE (ORAL)

Products Affected

- Cystagon

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Cystagon and Procysbi
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	1 year
Other Criteria	Cystinosis, nephropathic-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DALFAMPRIDINE

Products Affected

- dalfampridine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	MS. If prescribed by, or in consultation with, a neurologist or MS specialist (initial and continuation).
Coverage Duration	Initial-4months, Continuation-1 year
Other Criteria	Initial-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has impaired ambulation as evaluated by an objective measure (e.g., timed 25 foot walk and multiple sclerosis walking scale-12). Continuation-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has responded to or is benefiting from therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DALIRESP

Products Affected

- Daliresp
- roflumilast

PA Criteria	Criteria Details
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 1 year.
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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DANYELZA

Products Affected

- Danyelza

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Neuroblastoma-Approve if the requested medication is used as subsequent therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DAURISMO

Products Affected

- Daurismo oral tablet 100 mg, 25 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medications that will be used in combination, comorbidities
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	AML - approve if Daurismo will be used in combination with cytarabine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DEFERASIROX

Products Affected

- deferasirox

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Serum ferritin level
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DEFERIPRONE

Products Affected

- deferiprone

PA Criteria	Criteria Details
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	Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias Initial therapy - approve. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DIACOMIT

Products Affected

- Diacomit

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis.
Age Restrictions	6 months and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-Initial therapy-approve if the patient is concomitantly receiving clobazam or is unable to take clobazam due to adverse events. Dravet Syndrome-Continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DIMETHYL FUMARATE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
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
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DOPTELET

Products Affected

- Doptelet (10 tab pack)
- Doptelet (15 tab pack)
- Doptelet (30 tab pack)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, platelet count, date of procedure (Thrombocytopenia with chronic liver disease)
Age Restrictions	18 years and older (for chronic ITP-initial therapy only)
Prescriber Restrictions	Chronic ITP-prescribed by or after consultation with a hematologist (initial therapy)
Coverage Duration	Thrombo w/chronic liver disease-5 days, chronic ITP-initial-3 months, cont-1 year
Other Criteria	Thrombocytopenia with chronic liver disease-Approve if the patient has a current platelet count less than 50 x 109/L AND the patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. Chronic ITP initial-approve if the patient has a platelet count less than 30,000 microliters or less than 50,000 microliters and is at an increased risk of bleeding and has tried one other therapy or if the patient has undergone splenectomy. Continuation-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DUPIXENT

Products Affected

- Dupixent Pen subcutaneous pen injector 200 mg/1.14 mL, 300 mg/2 mL
- Dupixent Syringe subcutaneous syringe 100 mg/0.67 mL, 200 mg/1.14 mL, 300 mg/2 mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody.
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials
Age Restrictions	AD-6 months and older, asthma-6 years of age and older, Esophagitis-12 and older, Chronic Rhinosinusitis/Prurigo nodularis-18 and older
Prescriber Restrictions	Atopic Dermatitis/prurigo nodularis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Esophagitis-presc/consult-allergist or gastro
Coverage Duration	AD-Init-4mo, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/prurigo nod-init-6 mo, cont 1 yr
Other Criteria	AD,Init-pt 2yrs and older-pt meets a and b:a.used at least 1 med,med-high,high, and/or super-high-potency rx top CS OR AD affecting ONLY face,eyes/lids,skin folds,and/or genitalia and tried tacrolimus oint AND b.Inadeq efficacy was demonstrated w/prev tx.AD,Init-pt between 6 mo and less than 2 yr-pt meets a and b:a.used at least 1 med,med-high,high, and/or super-high-potency rx top CS and b.inadeq efficacy was demonstrated w/prev tx OR AD affecting ONLY face,eyes/lids,skin folds,and/or genitalia.Cont-pt responded to Dupixent.Asthma,init-pt meets (i, ii, and iii):i.Pt meets (a or b):a)blood eosinophil greater than or equal to 150 cells per microliter w/in prev 6 wks or within 6 wks prior to tx with any IL tx or Xolair OR b)has oral CS-dependent asthma, AND ii.received combo tx w/following (a and b): a)ICS AND b)1 add asthma control/maint med(NOTE:exception to the requirement for a trial of 1 add asthma controller/maint med can be made if pt already received anti-IL-5 tx or Xolair used concomitantly w/an ICS AND iii.asthma uncontrolled or was

PA Criteria	Criteria Details
	uncontrolled prior to starting anti-IL tx or Xolair defined by 1 (a, b, c, d or e): a)exper 2 or more asthma exacer req tx with systemic CS in prev yr OR b)exper 1 or more asthma exacer requiring hosp or ED visit in prev yr OR c)FEV1 less than 80percent predicted OR d)FEV1/FVC less than 0.80 OR e)asthma worsens w/tapering of oral CS tx.Cont-pt meets (i and ii): i.cont to receive tx with 1 ICS or 1 ICS-containing combo inhaler AND ii.has responded to Dupixent.Chronic rhinosinusitis w/nasal polyposis,init-pt receiving tx with an intranasal CS and experi rhinosinusitis symptoms like nasal obstruction, rhinorrhea, or reduction/loss of smell AND meets 1 (a or b): a)received tx w/syst CS w/in prev 2 yrs or has contraindication to systemic CS tx OR b)prior surgery for nasal polyps. Cont-pt cont to receive tx with an intranasal CS and responded to Dupixent. Eosino esoph, init-weighs greater than or equal to 40 kg, has dx of eosino esophagitis confirmed by endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, and does not have a secondary cause of eosino esophagitis, and has received at least 8 wks of tx with a Rx strength PPI. Cont-pt received at least 6mo of tx with Dupixent and has experi reduced intraepithelial eosinophil count or decreased dysphagia/pain upon swallowing or reduced frequency/severity of food impaction.Prurigo Nod, init-pt has greater than or equal to 20 nodular lesions and pt has experienced pruritus at least 6 wks, AND pt tried at least 1 high- or super-high-potency Rx topical CS. Cont-pt received at least 6 mo of tx with Dupixent and has experi reduced nodular lesion count, decreased pruritis or reduced nodular lesion size.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ELAPRASE

Products Affected

- Elaprase

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, serum or plasma OR a molecular genetic test demonstrating iduronate-2-sulfatase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ELREXFIO

Products Affected

- Elrexfio

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Multiple myeloma-approve if per FDA approved labeling the patient has tried at least four systemic regimens and among the previous regimens tried, the patient has received at least one drug from each of the following classes: proteasome inhibitor, an immunomodulatory drug and an anti-CD38 monoclonal antibody.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ELZONRIS

Products Affected

- Elzonris

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EMGALITY

Products Affected

- Emgality Pen
- EMGALITY SUBCUTANEOUS SYRINGE 120 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Aimovig, Vyepti or Ajovy
Required Medical Information	Diagnosis, number of migraine or cluster headaches per month, prior therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Cluster headache tx-6 months, migraine prevention-1 year
Other Criteria	Migraine headache prevention-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 one standard prophylactic pharmacologic therapy (e.g., anticonvulsant, beta-blocker), and has had inadequate response or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try a standard prophylactic pharmacologic therapy. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENBREL

Products Affected

- Enbrel Mini
- Enbrel subcutaneous solution
- Enbrel subcutaneous syringe
- Enbrel SureClick

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	PP-4 years and older (initial therapy)
Prescriber Restrictions	Initial only-RA/AS/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	1 year
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 systemic therapy for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID), biologic 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, 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)

PA Criteria	Criteria Details
	OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD-approve. Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Behcet's, GVHD-Cont-if the patient has had 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Graft versus host disease (GVHD), Behcet's disease
Part B Prerequisite	No

ENTYVIO

Products Affected

- Entyvio

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) used for an Inflammatory Condition
Required Medical Information	N/A
Age Restrictions	CD/UC - adults (initial therapy)
Prescriber Restrictions	CD/UC initial - Prescribed by or in consultation with a gastroenterologist. (initial therapy)
Coverage Duration	CD/UC - initial 14 weeks, cont 1 year
Other Criteria	CD Initial - the patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient OR the patient has tried one conventional systemic therapy for Crohn's disease (e.g., azathioprine, 6-mercaptopurine, or methotrexate) OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). Note: an exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried a biologic. Cont tx - had a response to Entyvio, as determined by the prescribing physician. UC initial-the patient has had a trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone). NOTE: A trial of a biologic (e.g., an adalimumab product [e.g., Humira], an infliximab product [e.g., Remicade, Inflectra, or Renflexis], or Simponi [golimumab for SC injection]) also counts as a trial of one systemic agent for UC. Cont tx - had a response to Entyvio (for example, decreased stool frequency or rectal bleeding), as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

EPCLUSA

Products Affected

- Epclusa oral pellets in packet 150-37.5 mg, 200-50 mg
- Epclusa oral tablet 200-50 mg, 400-100 mg

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin.
Required Medical Information	Genotype (including unknown), prescriber specialty, other medications tried or used in combination with requested medication
Age Restrictions	3 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No

EPIDIOLEX

Products Affected

- Epidiolex

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	Patients 1 year and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or if the patient has tried or is concomitantly receiving one of Diacomit or clobazam or Fintepla. Lennox Gastaut Syndrome-approve if the patient has tried or is concomitantly receiving at least two other antiepileptics drugs. Tuberous Sclerosis Complex-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Continuation of therapy-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EPKINLY

Products Affected

- Epkinly

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-cell lymphoma - approve if the patient has received two or more lines of systemic therapy and the medication will be given as a single agent. Human immunodeficiency virus (HIV)-Related B-Cell Lymphoma - approve if the patient has received two or more lines of systemic therapy and the medication will be given as a single agent. Note: HIV-related B-cell lymphomas includes HIV-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus-8 (HHV8) positive DLBCL. Post-transplant lymphoproliferative disorders - approve if the patient has received two or more lines of systemic therapy and the medication will be given as a single agent.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Human immunodeficiency virus (HIV)-Related B-Cell Lymphoma. Post-transplant lymphoproliferative disorders.
Part B Prerequisite	No

EPOETIN ALFA

Products Affected

- Procrit
- Retacrit

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	CRF anemia in patients 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, Mircera or Aranesp. 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 - Hgb is less than or equal to 13, surgery is elective, nonvascular and non-cardiac and 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, myelofibrosis- prescribed by or in consultation with, a hematologist or oncologist.
Coverage Duration	Chemo-6m,Transfus-1m, CKD-1yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr
Other Criteria	Myelofibrosis-Initial-patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 Mu/mL. Cont-approve if according to the prescriber the patient has had a response. Anemia in patients with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anemia due to myelodysplastic syndrome (MDS), Myelofibrosis

PA Criteria	Criteria Details
Part B Prerequisite	No

ERIVEDGE

Products Affected

- Erivedge

PA Criteria	Criteria Details
Exclusion Criteria	BCC (La or Met) - must not have had disease progression while on Odomzo.
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
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. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway. Basal cell carcinoma, metastatic-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central nervous System Cancer
Part B Prerequisite	No

ERLEADA

Products Affected

- Erleada oral tablet 240 mg, 60 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) agonist or the medication is concurrently used with Firmagon or if the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ERLOTINIB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Advanced or Metastatic NSCLC, approve if the patient has sensitizing EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of sensitizing EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. Advanced RCC, approve if the patient has recurrent or advanced non-clear cell histology RCC or if the patient had hereditary leiomyomatosis and renal cell carcinoma and erlotinib will be used in combination with bevacizumab. Bone cancer-approve if the patient has chordoma and has tried one previous therapy. Pancreatic cancer-approve if the medication is used in combination with gemcitabine and if the patient has locally advanced, metastatic or recurrent disease. Vulvar cancer-approve if the patient has advanced, recurrent or metastatic disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma.
Part B Prerequisite	No

ESBRIET

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
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	1 year
Other Criteria	IPF - must have FVC greater than or equal to 40 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EVEROLIMUS

Products Affected

- everolimus (antineoplastic) oral tablet
- everolimus (antineoplastic) oral tablet for suspension 2 mg, 3 mg, 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer-HER2 status, hormone receptor (HR) status.
Age Restrictions	All dx except TSC associated SEGA or partial onset seizures-18 years and older.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Breast Cancer-approve if pt meets ALL the following (A, B, C, D, E, and F):A)pt has recurrent or metastatic,HR+ disease AND B)pt has HER2-negative breast cancer AND C)pt has tried at least 1 prior endocrine therapy AND D)pt meets 1 of the following conditions (i or ii):i.pt is a postmenopausal woman or man OR ii.pt is pre/perimenopausal woman AND is receiving ovarian suppression/ablation with a GnRH agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND E)pt meets 1 of the following conditions (i or ii): i.Afinitor will be used in combo with exemestane and pt meets 1 of the following:pt is male and is receiving a GnRH analog or pt is a woman or ii. Afinitor will be used in combo with fulvestrant or tamoxifen AND F)pt has not had disease progression while on Afinitor. RCC, relapsed or Stage IV disease-approve if using for non-clear cell disease or if using for clear cell disease, pt has tried 1 prior systemic therapy (e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).TSC Associated SEGA-approve if pt requires therapeutic intervention but cannot be curatively resected. Thymomas and Thymic Carcinomas-approve if pt has tried chemotherapy or cannot tolerate chemotherapy. TSC associated renal angiomyolipoma -approve. WM/LPL - approve if pt has progressive or relapsed disease or if pt has not responded to primary therapy. Thyroid Carcinoma, differentiated-approve

PA Criteria	Criteria Details
	if pt is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if Afinitor will be used in combo with letrozole. GIST-approve if pt has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock or imatinib AND there is confirmation that Afinitor will be used in combo with 1 of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. TSC-associated partial-onset seizures-approve. NET tumors of the pancreas, GI Tract, Lung and Thymus (carcinoid tumors)-approve. Meningioma-approve if pt has recurrent or progressive disease. Soft tissue sarcoma-approve if pt has perivascular epithloid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangioleiomyomatosis. Classic hodgkin lymphoma-approve if pt has relapsed or refractory disease. Histiocytic neoplasm-approve if pt has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis with bone disease, central nervous system lesions, multisystem disease or pulmonary disease. Patient must also have PIK3CA mutation.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	neuroendocrine tumors of the thymus (Carcinoid tumors). Soft tissue sarcoma, classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST), Meningioma, men with breast cancer, pre/peri-menopausal women with breast cancer, Histiocytic Neoplasm
Part B Prerequisite	No

EXKIVITY

Products Affected

- Exkivity

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-approve if the patient meets (A, B and C): A) Patient has locally advanced or metastatic NSCLC AND B) Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation, as determined by an approved test AND C) Patient has previously tried at least one platinum-based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EYLEA

Products Affected

- Eylea

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Administered by or under the supervision of an ophthalmologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FABRAZYME

Products Affected

- Fabrazyme

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient alpha-galactosidase A activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating mutations in the galactosidase alpha gene.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FASENRA

Products Affected

- Fasenra
- Fasenra Pen

PA Criteria	Criteria Details
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	Initial - must have peripheral blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks (prior to treatment with any anti-interleukin (IL)-5 therapy) AND meet both of the following criteria: 1) Patient has received combination therapy with an inhaled corticosteroid AND one of the following: inhaled LABA, inhaled long-acting muscarinic antagonist, Leukotriene receptor antagonist, or Theophylline, AND 2) Patient's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by ONE of the following: a) patient experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, OR b) patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, OR c) patient has a FEV1 less than 80 percent predicted, OR d) Patient has an FEV1/FVC less than 0.80, OR e) Patient's asthma worsens upon tapering of oral corticosteroid therapy. NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an ICS. Continuation - The patient has responded to Fasenra 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

PA Criteria	Criteria Details
	corticosteroid therapy) AND patient continues to receive therapy with an inhaled corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FINTEPLA

Products Affected

- Fintepla

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex, Clobazam or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome, initial-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome, continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FIRDAPSE

Products Affected

- Firdapse

PA Criteria	Criteria Details
Exclusion Criteria	History of seizures (initial therapy)
Required Medical Information	Diagnosis, seizure history, lab and test results
Age Restrictions	6 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist (initial therapy)
Coverage Duration	Initial-3 months, Cont-1 year
Other Criteria	Initial therapy-Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive nerve stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. Continuation-patient continues to derive benefit (e.g., improved muscle strength, improvements in mobility) from Firdapse, according to the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FOTIVDA

Products Affected

- Fotivda

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years
Other Criteria	Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. Note: Examples of systemic regimens for renal cell carcinoma include axitinib tablets, axitinib + pembrolizumab injection, cabozantinib tablets, cabozantinib + nivolumab injection, sunitinib malate capsules, pazopanib tablets, sorafenib tablets, and lenvatinib capsules + everolimus.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FYARRO

Products Affected

- Fyarro

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Perivascular Epithelioid Cell Tumor (PEComa), Malignant-approve if the patient has locally advanced unresectable disease or metastatic disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GATTEX

Products Affected

- Gattex 30-Vial
- Gattex One-Vial

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced improvement.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GAVRETO

Products Affected

- Gavreto

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years and older, MTC/thyroid cancer-12 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	NSCLC-approve if the patient has metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Medullary thyroid cancer (MTC)-approve if the patient has advanced or metastatic rearranged during transfection (RET)-mutant disease and the disease requires treatment with systemic therapy. Thyroid cancer (other than MTC)-approve if the patient has advanced or metastatic rearranged during transfection (RET) fusion-positive disease, the disease is radioactive iodine-refractory AND the disease requires treatment with systemic therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GILENYA

Products Affected

- fingolimod
- Gilenya oral capsule 0.5 mg

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of fingolimod with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
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	For patients requesting brand name Gilenya, Initial treatment-approve if the patient has tried generic dimethyl fumarate or fingolimod, unless the patient meets one of the following: a)patient is greater than or equal to 10 years of age but less than 18 years old or, b) if the patient has highly active or aggressive multiple sclerosis defined as, rapidly advancing deterioration in physical functioning (Note: examples include loss of mobility or lower levels of ambulation, severe changes in strength or coordination), or c) disabling relapse with suboptimal response to systemic corticosteroids, or d) Magnetic resonance imaging (MRI) findings suggest highly active or aggressive multiple sclerosis (Note: Examples include new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions) or, e) manifestation of multiple sclerosis-related cognitive impairment. Note: Prior use of brand Tecfidera, Bafiertam, Vumerity or a glatiramer product (brand or generic) with inadequate efficacy or significant intolerance (according to the prescriber) also counts. Cont tx - approve if the patient has been established on Gilenya.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GILOTRIF

Products Affected

- Gilotrif

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For NSCLC - EGFR exon deletions or mutations, or if NSCLC is squamous cell type
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	NSCLC EGFR pos - For the treatment of advanced or metastatic non small cell lung cancer (NSCLC) - approve if the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: examples of sensitizing EGFR mutation-positive NSCLC include the following mutations : exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. NSCLC metastatic squamous cell must have disease progression after treatment with platinum based chemotherapy. Head and neck cancer-approve if the patient has non-nasopharyngeal head and neck cancer and the patient has disease progression on or after platinum based chemotherapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Head and neck cancer
Part B Prerequisite	No

GLATIRAMER

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Products Affected

- Bydureon BCise
- Byetta subcutaneous pen injector 10 mcg/dose(250 mcg/mL) 2.4 mL, 5 mcg/dose (250 mcg/mL) 1.2 mL
- Mounjaro
- Ozempic subcutaneous pen injector 0.25 mg or 0.5 mg (2 mg/3 mL), 1 mg/dose (4 mg/3 mL), 2 mg/dose (8 mg/3 mL)
- Rybelsus
- Trulicity
- Victoza 2-Pak
- Victoza 3-Pak

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GNRH AGONIST IMPLANTS

Products Affected

- Zoladex

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Endometriosis-18 years and older
Prescriber Restrictions	Prostate cancer/Breast cancer-prescribed by or in consultation with an oncologist. Endometriosis/abnormal uterine bleeding-prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health.
Coverage Duration	Abnormal uterine bleeding-2 months, Breast/prostate cancer/puberty-1 year, Endometriosis-6 months
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast cancer- Zoladex 3.6 mg is used in premenopausal or perimenopausal women. Abnormal uterine bleeding-Zoladex 3.6mg is used as an endometrial-thinning agent prior to endometrial ablation.Endometriosis-approve Zoladex 3.6 mg. Prostate cancer-approve Zoladex 3.6 mg and/or 10.8 mg.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

Products Affected

- leuprolide subcutaneous kit
- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)
- Lupron Depot-Ped
- Lupron Depot-Ped (3 month)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prostate cancer-prescr/consult with oncologist or urologist. For the treatment of other cancer diagnosis must be prescribed by or in consultation with an oncologist.
Coverage Duration	uterine leiomyomata approve 3months/all other dx 12 mo
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ovarian cancer, breast cancer, prophylaxis or treatment of uterine bleeding or menstrual suppression in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors
Part B Prerequisite	No

GRALISE/HORIZANT/LYRICA CR

Products Affected

- Gralise oral tablet extended release 24 hr
  300 mg, 450 mg, 600 mg, 750 mg, 900 mg

PA Criteria	Criteria Details
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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GROWTH HORMONES

Products Affected

- Omnitrope

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	GHD in Children/Adolescents. Pt meets one of the following-1-had 2 GH stim tests with the following-levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are inadequate as defined by a peak GH response which is below the normal reference range of the testing laboratory OR had at least 1 GH test and results show inadequate response and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). 2.brain radiation or tumor resection and pt has 1 GH stim test and results is inadequate response or has def in at least 1 other pituitary hormone (that is, ACTH, TSH, gonadotropin deficiency [LH and/or FSH] are counted as 1 def], or prolactin).3. congenital hypopituitarism and has one GH stim test with inadequate response OR def in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk 4.pt has panhypopituitarism and has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on MRI or CT or pt has 3 or more pituitary hormone deficiencies or pt has had one GH test and results were inadequate 5.pt had a hypophysectomy. Cont-pt responding to therapy
Age Restrictions	ISS 5 y/o or older, SGA 2 y/o or older, SBS 18 y/o or older
Prescriber Restrictions	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.
Coverage Duration	ISS - 6 mos initial, 12 months cont tx, SBS 1 month, others 12 mos

PA Criteria	Criteria Details
Other Criteria	GHD initial in adults and adolescents 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. has known mutations, embryonic lesions, congenital or genetic defects or structural hypothalamic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 AND if a transitional adolescent must be off tx for at least one month before retesting. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal to 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - prescriber confirms response to therapy. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy.Cont Tx for CKD, Noonan, PW in child/adolescents, SHOX, and TS - prescriber confirms response to therapy. SBS initial pt receiving specialized nutritional support. Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	CKD, SHOX, SBS

PA Criteria	Criteria Details
Part B Prerequisite	No

HARVONI

Products Affected

- Harvoni oral pellets in packet 33.75-150 mg, 45-200 mg
- Harvoni oral tablet 45-200 mg, 90-400 mg

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	N/A
Age Restrictions	3 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No

HETLIOZ

Products Affected

- Hetlioz
- tasimelteon

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Non-24-patient is totally blind with no perception of light
Age Restrictions	Non-24-18 years or older (initial and continuation), SMS-16 years and older
Prescriber Restrictions	prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders (initial and continuation)
Coverage Duration	6 mos initial, 12 mos cont
Other Criteria	Initial - patient is totally blind with no perception of light, 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 plus evaluation of sleep logs. Cont - Approve if patient is totally blind with no perception of light and pt 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). Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HIGH RISK MEDICATIONS - BENZODIAZEPINES

Products Affected

- clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg
- diazepam injection
- Diazepam Intensol
- diazepam oral concentrate
- diazepam oral solution
- diazepam oral tablet
- lorazepam injection solution
- lorazepam injection syringe 2 mg/mL
- Lorazepam Intensol
- lorazepam oral concentrate
- lorazepam oral tablet 0.5 mg, 1 mg, 2 mg

PA Criteria	Criteria Details
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, approve if the physician has assessed risk versus benefit in using the High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy. 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 and the physician has assessed risk versus benefit in using the HRM in this patient and has confirmed that he/she would still like initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HIGH RISK MEDICATIONS - BENZTROPINE

Products Affected

- benztropine oral

PA Criteria	Criteria Details
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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

Products Affected

- cyclobenzaprine oral tablet 10 mg, 5 mg

PA Criteria	Criteria Details
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

Products Affected

- diphenhydramine HCl oral elixir
- hydroxyzine HCl oral tablet
- promethazine oral

PA Criteria	Criteria Details
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 hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HIGH RISK MEDICATIONS - PHENOBARBITAL

Products Affected

- phenobarbital

PA Criteria	Criteria Details
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HIGH RISK MEDICATIONS- ESTROGENS

Products Affected

- Amabelz
- Dotti
- estradiol oral
- estradiol transdermal patch semiweekly
- estradiol transdermal patch weekly
- estradiol-norethindrone acet
- Fyavolv
- Jinteli
- Lyllana
- Menest
- Mimvey
- norethindrone ac-eth estradiol oral tablet 0.5-2.5 mg-mcg, 1-5 mg-mcg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Previous medication use
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	For the treatment of Vulvar Vaginal Atrophy, approve if the patient has had a trial of one of the following for vulvar vaginal atrophy (brand or generic): Estradiol Vaginal Cream, Estring,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. 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HUMIRA

Products Affected

- Humira Pen
- Humira Pen Crohns-UC-HS Start
- Humira Pen Psor-Uveits-Adol HS
- Humira subcutaneous syringe kit 40 mg/0.8 mL
- Humira(CF) Pedi Crohns Starter subcutaneous syringe kit 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL
- Humira(CF) Pen Crohns-UC-HS
- Humira(CF) Pen Pediatric UC
- Humira(CF) Pen Psor-Uv-Adol HS
- Humira(CF) Pen subcutaneous pen injector kit 40 mg/0.4 mL, 80 mg/0.8 mL
- Humira(CF) subcutaneous syringe kit 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL

PA Criteria	Criteria Details
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 (initial therapy only). Ulcerative colitis (UC) 5 or older (initial therapy only), PP-18 or older (initial therapy only)
Prescriber Restrictions	Initial therapy only for all dx-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	1 year
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 one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (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,

PA Criteria	Criteria Details
	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. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IBRANCE

Products Affected

- Ibrance

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer - approve recurrent or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Ibrance will be used 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 meets one of the following conditions: Ibrance will be used in combination with anastrozole, exemestane, or letrozole or Ibrance will be used in combination with fulvestrant 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 analog AND Ibrance with be used in combination with anastrozole, exemestane or letrozole or Ibrance will be used in combination with fulvestrant 4. Pt is postmenopausal AND Ibrance will be used in combination with fulvestrant. Liposarcoma-approve if the patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Liposarcoma, pre/peri-menopausal women with breast cancer in combination with an aromatase inhibitor

PA Criteria	Criteria Details
Part B Prerequisite	No

ICATIBANT

Products Affected

- icatibant
- Sajazir

PA Criteria	Criteria Details
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 1 year.
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant - the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ICLUSIG

Products Affected

- Iclusig

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Approve if the patient meets one of the following: 1. Patient has CML or ALL that is Ph+, T315I positive or, 2. patient has CML, chronic phase with resistance or intolerance to at least two prior TKIs or, 3. patient has accelerated phase or blast phase CML or Philadelphia chromosome positive ALL for whom no other TKIs are indicated. GIST - approve if the patient tried all of the FDA-approved therapies first to align with NCCN recommendations which include: Imatinib or Ayvakit (avapritinib tablets), AND Sunitinib or Sprycel (dasatinib tablets), AND Stivarga (regorafenib tablets), AND Qinlock (ripretinib tablets). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has ABL1 rearrangement or FGFR1 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia
Part B Prerequisite	No

IDHIFA

Products Affected

- Idhifa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	IDH2-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	AML - approve if the patient is IDH2-mutation status positive as detected by an approved test
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ILARIS

Products Affected

- Ilaris (PF)

PA Criteria	Criteria Details
Exclusion Criteria	When used in combination with concurrent biologic therapy (e.g.TNF antagonists, etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or rilonacept.
Required Medical Information	N/A
Age Restrictions	CAPS-4 years of age and older. SJIA-2 years of age and older. Still's disease-18 years and older (Note-patients less than 18 should be refered to criteria for systemic juvenil idiopathic arthritis). Acute gout flare-18 years of age and older
Prescriber Restrictions	CAPS/MWS/FCAS initial- Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. SJIA/Still's disease (initial), Acute gout flare (initial/cont)- prescribed by or in consultation with a rheumatologist. FMF initial - rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, hematologist. HIDS/MKD/TRAPS initial - rheumatologist, nephrologist, geneticist, oncologist, hematologist.
Coverage Duration	CAPS/SJIA-3moinit,1yrcont.FMF/HIDS/MKD/TRAPS-4moinit,1yrcont.Stills-3moinit,1yrcont.Acutegoutfl-6mo
Other Criteria	For renewal of CAPS/MWS/FCAS/SJIA/FMF/HIDS/MKD/TRAPS/Still's - After pt had been started on Ilaris, approve if the pt had a response to therapy as determined by prescribing physician. SJIA, initial therapy - approve if the pt meets one of the following: 1. has tried at least 2 other biologics for SJIA (tocilizumab, abatacet, TNF antagonists (e.g. etanercept, adalimumab, infliximab) OR 2. pt has features of poor prognosis (e.g. arthritis of the hip, radiographic damage, 6-month duration of significant active systemic disease, defined by fever, elevated inflammatory markers, or requirement for treatment with systemic glucocorticoids AND tried Actemra or Kineret OR 3. Pt has features of SJIA with active systemic features with concerns of progression to macrophage activation syndrome (MAS) [as determined by the prescribing physician] AND has tried Kineret. Still's Disease-Initial-approve if the patient has tried at least TWO

PA Criteria	Criteria Details
	other biologics or patient has features of poor prognosis and has tried Actemra or Kineret or patient has active systemic features with concerns of progression to macrophage activation syndrome (MAS) and has tried Kineret. Acute gout flare- approve if (i and ii): (i) pt has intolerance, contraindication, or lack of response to NSAIDs and colchicine for the treatment of acute gout flares OR pt is unable to be retreated with a repeat course of corticosteroids (oral or injectable) for acute gout flare, and (ii) patient is receiving or will be taking concomitant urate lowering medication for prevention of gout unless contraindicated (ex: allopurinol, febuxostat, probenecid).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IMATINIB

Products Affected

- imatinib oral tablet 100 mg, 400 mg

PA Criteria	Criteria Details
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	ASM, DFSP, HES, MDS/MPD/Myeloid/Lymphoid Neoplasms-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	For ALL/CML, must have Ph-positive for approval of imatinib.Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or according to the prescriber, the patient cannot take Turalio. Myelodysplastic/myeloproliferative disease-approve if the condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.Graft versus host disease, chronic-approve if the patient has tried at least one conventional systemic treatment (e.g., imbruvica). Metastatic melanoma-approve if the patient has c-Kit-positive advanced/recurrent or metastatic melanoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement or an FIP1L1-PDGFRA or PDGFRB rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chordoma, advanced, aggressive or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia.

PA Criteria	Criteria Details
Part B Prerequisite	No

IMBRUVICA

Products Affected

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

PA Criteria	Criteria Details
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	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma (e.g., gastric MALT lymphoma, nongastric MALT lymphoma, AIDS related, post-transplant lymphoproliferative disorder).
Part B Prerequisite	No

IMJUDO

Products Affected

- Imjudo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	HCC-30 days, NSCLC-6 months
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. HCC-approve if the patient has metastatic or unresectable disease, or the patient is not a surgical candidate, Imjudo will be used as first-line systemic therapy in combination with Imfinzi. NSCLC-approve if the patient meets all of the following: has recurrent, advanced or metastatic disease, tumor is negative for epidermal growth factor receptor (EGFR) mutation and negative for anaplastic lymphoma kinase (ALK) genomic tumor abberations and Imjudo will be used as first line systemic therapy in combination with Imfinzi.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INGREZZA

Products Affected

- Ingrezza
- Ingrezza Initiation Pack

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	TD - Prescribed by or in consultation with a neurologist or psychiatrist. Chorea HD - prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Chorea associated with Huntington's Disease- approve if diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- testosterone cypionate
- testosterone enanthate

PA Criteria	Criteria Details
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	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
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 enanthate. Breast cancer in females-approve testosterone enanthate. 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. Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note: For a

PA Criteria	Criteria Details
	patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).
Part B Prerequisite	No

INLYTA

Products Affected

- Inlyta oral tablet 1 mg, 5 mg

PA Criteria	Criteria Details
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. Soft tissue sarcoma-approve if the patient has alveolar soft part sarcoma and the medication will be used in combination with Keytruda (pembrolizumab).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma, Soft tissue sarcoma
Part B Prerequisite	No

INPEFA

Products Affected

- Inpefa oral tablet 200 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Heart Failure, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit-approve. Type 2 Diabetes, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit-approve if the patient has chronic kidney disease AND has one or more cardiovascular risk factor(s).Note: Patients with heart failure should be reviewed under criteria for Heart Failure.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INQOVI

Products Affected

- Inqovi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Neoplasms
Part B Prerequisite	No

INREBIC

Products Affected

- Inrebic

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has intermediate-2 or high-risk disease. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid Neoplasms with Eosinophilia
Part B Prerequisite	No

IRESSA

Products Affected

- gefitinib
- Iressa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	NSCLC-approve if the patient has advanced or metastatic disease and the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IVERMECTIN (ORAL)

Products Affected

- ivermectin oral

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	30 days
Other Criteria	Pediculosis-approve if the patient has infection caused by pediculus humanus capitis (head lice), pediculus humanus corporis (body lice), or has pediculosis pubis caused by phthirus pubis (pubic lice). Scabies-approve if the patient has classic scabies, treatment resistant scabies, is unable to tolerate topical treatment, has crusted scabies or is using ivermectin tablets for prevention and/or control of scabies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, Mansonella ozzardi infection, Mansonella streptocerca infection, Pediculosis, Scabies. Trichuriasis, Wucheria bancrofti infection
Part B Prerequisite	No

IVIG

Products Affected

- Privigen

PA Criteria	Criteria Details
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

JAKAFI

Products Affected

- Jakafi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	ALL-less than 21 years of age, GVHD-12 and older, MF/PV/CMML-2/essential thrombo/myeloid/lymphoid neoplasm-18 and older
Prescriber Restrictions	N/A
Coverage Duration	GVHD-1 year, all others-3 years.
Other Criteria	For polycythemia vera patients must have tried hydroxyurea. ALL-approve if the mutation/pathway is Janus associated kinase (JAK)-related. GVHD, chronic-approve if the patient has tried one conventional systemic treatment for graft versus host disease. GVHD, acute-approve if the patient has tried one systemic corticosteroid. GVHD, acute-approve if the patient has tried one systemic corticosteroid. Polycythemia vera-approve if the patient has tried hydroxyurea. Atypical chronic myeloid leukemia-approve if the patient has a CSF3R mutation or a janus associated kinase mutation 2 (JAK2). Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent. Essential thrombocythemia-approve if the patient has tried hydroxyurea, peginterferon alfa-2a or anagrelide. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the tumor has a janus associated kinase 2 (JAK2) rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms

PA Criteria	Criteria Details
Part B Prerequisite	No

JAYPIRCA

Products Affected

- Jaypirca oral tablet 100 mg, 50 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Mantle cell lymphoma-approve if the patient has tried at least one systemic regimen or patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail), AND the patient has tried one Bruton tyrosine kinase inhibitor (BTK) for mantle cell lymphoma.Note: Examples of a systemic regimen contain one or more of the following products: rituximab, dexamethasone, cytarabine, carboplatin, cisplastin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, Velcade (bortezomib intravenous or subcutaneous injection), lenalidomide, gemcitabine, and Venclexta (venetoclax tablets). Note: Examples of BTK inhibitors indicated for mantle cell lymphoma include Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib capsules), and Imbruvica (ibrutinib capsules, tablets, and oral suspension). CLL/SLL-patient meets (A or B): A) patient has resistance or intolerance to Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules) or B) patient has relapsed or refractory disease and has tried a Bruton tyrosine kinase (BTK) inhibitor and Venclexta (venetoclax tablet)-based regimen. Examples of BTK inhibitor include: Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Chronic Lymphocytic Leukemia and Small Lymphocytic Leukemia
Part B Prerequisite	No

JEMPERLI

Products Affected

- Jemperli

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Colon/rectal/appendiceal cancer if being used for neoadjuvant therapy-6 months. All other dx-1 yr.
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Endometrial cancer-approve. Mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) Solid tumors-approve if the patient has progressed on or after prior treatment and according to the prescriber, the patient does not have any satisfactory alternative treatment options. Small Bowel Adenocarcioma-approve if the patient has dMMR or MSI-H disease and has advanced or metastatic disease and Jemperli will be used as initial therapy when the patient has received adjuvant oxaliplatin or has a contraindication to oxaliplatin OR Jemperli is used as subsequent therapy and the patient has NOT received oxaliplatin in the adjuvant setting and the patient does NOT have a contraindication to oxaliplatin. Colon, Rectal, or Appendiceal Cancer- approve if patient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease AND has advanced or metastatic disease AND is being used for neoadjuvant therapy or primary or subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Small Bowel Adenocarcinoma, Colon, Rectal or Appendiceal Cancer
Part B Prerequisite	No

JUXTAPID

Products Affected

- Juxtapid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
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) and had clinical manifestation of HoFH before the age of 10 years OR both parents of the patient had untreated (LDL-C levels or total cholesterol levels consistent with HeFH OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL and had clinical manifestation of HoFH before the age of 10 years OR both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with HeFH, AND 2) patient tried at least one PCSK9 inhibitor for greater than or equal to 8 continuous weeks and the LDL-C level after this PCSK9 inhibitor therapy remains greater than or equal to 70 mg/dL 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]) and the LDL-C level after these treatment regimens 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

PA Criteria	Criteria Details
	rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KADCYLA

Products Affected

- Kadcyla

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Breast Cancer-Recurrent/metastatic-1 yr, Breast Cancer-Adjuvant tx-approve 1 yr total, other-1yr
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease and the patient is using for recurrent or metastatic breast cancer OR if using for adjuvant therapy. NSCLC-approve if the disease has activating human epidermal growth factor receptor 2 (HER2) mutations and the patient has metastatic disease. Salivary gland tumor-approve if the patient has recurrent, unresectable, or metastatic disease and the patient has human epidermal growth factor receptor 2 (HER2)-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer (NSCLC), salivary gland tumor
Part B Prerequisite	No

KALYDECO

Products Affected

- Kalydeco oral granules in packet
- Kalydeco oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Orkambi, Trikafta or Symdeko
Required Medical Information	N/A
Age Restrictions	1 month of age and older
Prescriber Restrictions	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - must have one mutation in the CFTR gene that is responsive to the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KANUMA

Products Affected

- Kanuma

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient lysosomal acid lipase activity in leukocytes, fibroblasts, or liver tissue OR a molecular genetic test demonstrating lysosomal acid lipase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KERENDIA

Products Affected

- Kerendia

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with spironolactone or eplerenone
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Diabetic kidney disease, initial-approve if the patient meets the following criteria (i, ii and iii): i. Patient has a diagnosis of type 2 diabetes, AND ii. Patient meets one of the following (a or b): a)Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b)According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy, AND iii.At baseline (prior to the initiation of Kerendia), patient meets all of the following (a, b, and c): a)Estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73 m2 AND b)Urine albumin-to-creatinine ratio greater than or equal to 30 mg/g AND c)Serum potassium level less than or equal to 5.0 mEq/L. Diabetic kidney disease, continuation-approve if the patient meets the following criteria (i and ii): i.Patient has a diagnosis of type 2 diabetes, AND ii. Patient meets one of the following (a or b): a.Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b.According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

KEYTRUDA

Products Affected

- Keytruda

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 and older (except Merkel cell, MSI-H/dMMR tumors, large B-cell lymph, TMB-H, glioma) Glioma - less than 18 years old
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Adjuvant treatment of melanoma/RCC-approve up to 1 year total, all other dx-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	adrenal gland tumor, anal carcinoma, extranodal NK/T-Cell Lymphoma, nasal type, Gestational trophoblastic neoplasia, mycosis fungoides/Sezary syndrome, primary cutaneous anaplastic large cell lymphoma, small cell lung cancer, soft tissue sarcoma, squamous cell skin cancer, thymic carcinoma, vulvar cancer, glioma, Kaposi sarcoma
Part B Prerequisite	No

KIMMTRAK

Products Affected

- Kimmtrak

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Uveal melanoma-approve if the patient has unresectable or metastatic disease and if the tumor is HLA-A*02:01 positive.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KISQALI

Products Affected

- Kisqali Femara Co-Pack oral tablet 200 mg/day(200 mg x 1)-2.5 mg, 400 mg/day(200 mg x 2)-2.5 mg, 600 mg/day(200 mg x 3)-2.5 mg
- Kisqali oral tablet 200 mg/day (200 mg x 1), 400 mg/day (200 mg x 2), 600 mg/day (200 mg x 3)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer - approve recurrent or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Kisqali will be used 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 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 analog AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No

KORLYM

Products Affected

- Korlym

PA Criteria	Criteria Details
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	Endogenous Cushing's Synd-1 yr. Patients awaiting surgery or response after radiotherapy-4 months
Other Criteria	Endogenous Cushing's Syndrome-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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Endogenous Cushing's Syndrome, awaiting surgery. Patients with Endogenous Cushing's syndrome, awaiting a response after radiotherapy
Part B Prerequisite	No

KRAZATI

Products Affected

- Krazati

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LAPATINIB

Products Affected

- lapatinib

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which lapatinib 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 recurrent or metastatic breast cancer, approve if lapatinib will be used in combination with capecitabine OR trastuzumab and the patient has tried at least two prior anti-HER2 based regimens OR the medication will be used in combination with an aromatase inhibitor and and the patient has HR+ dusease and the patient is a postmenopausal woman or the patient is premenopausal or perimenopausal woman and is receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian irradiation OR the patient is a man and is receiving a GnRH analog. Colon or rectal cancer-approve if the patient has unresectable advanced or metastatic disease that is human epidermal receptor 2 (HER2) amplified and with wild-type RAS and BRAF disease and the patient has tried at least one chemotherapy regimen or is not a candidate for intensive therapy and the medication is used in combination with trastuzumab (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan) and the patient has not been previously treated with a HER2-inhibitor. Bone Cancer-approve if the patient has recurrent chordoma and if the patient has epidermal growth-factor receptor (EGFR)-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone cancer-chordoma, colon or rectal cancer

PA Criteria	Criteria Details
Part B Prerequisite	Yes

LENVIMA

Products Affected

- Lenvima

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
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 ALL of the following criteria: 1) pt has advanced disease AND if the patient meets i or ii-i. Lenvima is is being used in combination with Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b-a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND B) The medication is used in combination with Keytruda (pembrolizumab for intravenous injection) AND C)the disease has progressed on at least one prior systemic therapy AND D) The patient is not a candidate for curative surgery or radiation. Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. Melanoma - approve if the patient has unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Renal cell carcinoma with non-clear cell histology and Melanoma
Part B Prerequisite	No

LEUKINE

Products Affected

- Leukine injection recon soln

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Neuroblastoma-less than 18 years of age
Prescriber Restrictions	AML if prescribed by or in consultation with an oncologist or hematologist, PBPC/BMT - 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.Neuroblastoma-prescribed by or in consultation with an oncologist.
Coverage Duration	Radiation Syndrome/BMT - 1 mo, AML/Neuroblastoma-6 months, PBPC-14 days
Other Criteria	Neuroblastoma-approve if the patient is receiving Leukine in a regimen with dinutuximab.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neuroblastoma
Part B Prerequisite	No

LIBTAYO

Products Affected

- Libtayo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous surgeries or radiation
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Locally advanced or metastatic CSCC-approve if the patient is not a candidate for curative surgery or curative radiation. Basal Cell Carcinoma-approve if the patient has locally advanced or metastatic disease and has received previous treatment with at least one hedgehog pathway inhibitor or a hedgehog pathway inhibitor is not an appropriate therapy for the patient. NSCLC-approve if the patient has locally advanced disease and is not eligible for surgical resection or chemoradiation or if the patient has metastatic disease, the tumor proportion score (TPS) for programmed death ligand-1 (PD-L1) as determined by an approved test is greater than or equal to 50 percent AND the tumor is negative for actionable mutations.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LIDOCAINE PATCH

Products Affected

- lidocaine topical adhesive patch,medicated 5 %

PA Criteria	Criteria Details
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
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Diabetic neuropathic pain, chronic back pain
Part B Prerequisite	No

LONG ACTING OPIOIDS

Products Affected

- Belbuca
- buprenorphine transdermal patch
- hydromorphone oral tablet extended release 24 hr
- Methadone Intensol
- methadone oral concentrate
- methadone oral solution 10 mg/5 mL, 5 mg/5 mL
- methadone oral tablet 10 mg, 5 mg
- Methadose oral concentrate
- morphine oral tablet extended release
- OxyContin oral tablet,oral only,ext.rel.12 hr 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg

PA Criteria	Criteria Details
Exclusion Criteria	Acute (ie, non-chronic) pain
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried 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. Patients with cancer, in hospice, sickle cell disease or who reside in a long term care facility are not required to meet above criteria. 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.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LONSURF

Products Affected

- Lonsurf

PA Criteria	Criteria Details
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	Gastric or Gastroesophageal Junction Adenocarcinoma-approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma. Colon and rectal cancer-approve per labeling if the patient has been previously treated with a fluropyrimidine, oxaliplatin and irinotecan. If the patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type) they must also try Erbitux or Vectibix.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LORBRENA

Products Affected

- Lorbrena oral tablet 100 mg, 25 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, ALK status, ROS1 status, previous therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Erdheim Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has IMT with ALK translocation. NSCLC - Approve if the patient has ALK-positive metastatic NSCLC, as detected by an approved test. NSCLC-ROS1 Rearrangement-Positive, metastatic NSCLC-approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive, Erdheim Chester Disease, Inflammatory Myofibroblastic Tumor (IMT)
Part B Prerequisite	No

LOTRONEX

Products Affected

- alosetron

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LUMAKRAS

Products Affected

- Lumakras

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease, as determined by an approved test AND either (i or ii): (i) patient has locally advanced or metastatic disease and has been previously treated with at least one systemic regimen OR (ii) patient has recurrent disease after resection.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pancreatic Adenocarcinoma
Part B Prerequisite	No

LUMIZYME

Products Affected

- Lumizyme

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue OR patient has a molecular genetic test demonstrating acid alpha-glucosidase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LUMOXITI

Products Affected

- Lumoxiti

PA Criteria	Criteria Details
Exclusion Criteria	Creatinine clearance less than 30 ml/min
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	6 months
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. HCL-approve if the patient has tried at least two prior systemic therapies including therapy with a purine analog (cladribine and/or pentostatin).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LUNSUMIO

Products Affected

- Lunsumio

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consulation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. Follicular Lymphoma-approve if the patient has received at least two lines of systemic therapy. Note: Examples of systemic therapy include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (obinutuzumab intravenous infusion) and CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LYNPARZA

Products Affected

- Lynparza

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Ovarian Cancer - Treatment-initial-Approve if the patient meets the following criteria (i and ii): i. The patient has a germline BRCA-mutation as confirmed by an approved test AND has progressed on two or more prior lines of chemotherapy. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient meets one of the following criteria (A or B): A) The patient meets both of the following criteria for first-line maintenance therapy (i and ii): i. The patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND ii. The patient is in complete or partial response to first-line platinum-based chemotherapy regimen (e.g., carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin) OR B) The patient is in complete or partial response after at least two platinum-based chemotherapy regimens (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast cancer, recurrent or

PA Criteria	Criteria Details
	metastatic disease-approve if the patient has recurrent or metastatic disease, and has germline BRCA mutation-positive breast cancer. Pancreatic Cancer-maintenance therapy-approve if the patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate cancer-castration resistant-approve if the patient has metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or the pateint has had a bilateral orchiectomy, and the patient meets either (i or ii): i) the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test and the patient has been previously treated with at least one androgen receptor directed therapy or ii) the patient has a BRCA mutation and the medication is used in combination with abiraterone plus one of prednisone or prednisolone. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma
Part B Prerequisite	No

LYTGOBI

Products Affected

- Lytgobi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements as detected by an approved test and if the patient has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, and gemcitabine + cisplatin + Abraxane.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MARGENZA

Products Affected

- Margenza

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer, recurrent or metastatic-approve if the patient meets A, B, C and D: A) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease AND B) Patient has tried at least two prior anti-HER2 regimens AND C) At least one of the prior anti-HER2 regimen was used for metastatic disease AND D) The medication is used in combination with chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MEGACE

Products Affected

- megestrol oral suspension 400 mg/10 mL (10 mL), 400 mg/10 mL (40 mg/mL), 625 mg/5 mL (125 mg/mL)
- megestrol oral tablet

PA Criteria	Criteria Details
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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MEKINIST

Products Affected

- Mekinist oral recon soln
- Mekinist oral tablet 0.5 mg, 2 mg

PA Criteria	Criteria Details
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	6 years and older
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. Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for low-grade serous carcinoma. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafinlar. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i) adjuvant treatment of one of the following conditions: pilocytic astrocytoma or pleomorphic xanthoastrocytoma or ganglioglioma, OR ii) recurrent disease for one of the following conditions: low-grade glioma OR anaplastic glioma OR glioblastoma, OR iii) melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Tafinlar (dabrafenib). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the

PA Criteria	Criteria Details
	following: multisystem disease or pulmonary disease or central nervous system lesions or patient has Erdheim Chester disease or Rosai-Dorfman disease AND patient has BRAF V600-mutation positive disease. Metastatic or Solid Tumors-Approve if the patient meets the following (A, B, and C): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafinlar (dabrafenib capsules), AND C) Patient has no satisfactory alternative treatment options.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Biliary Tract Cancer, Central Nervous System Cancer, Histiocytic Neoplasm
Part B Prerequisite	No

MEKTOVI

Products Affected

- Mektovi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status, concomitant medications
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. Histiocytic neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. multisystem disease OR, ii. pulmonary disease or, iii. central nervous system lesions. NSCLC-approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Braftovi (encorafenib capsules).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic Neoplasms
Part B Prerequisite	No

MEMANTINE

Products Affected

- memantine oral capsule,sprinkle,ER 24hr
- memantine oral solution
- memantine oral tablet
- Namzaric

PA Criteria	Criteria Details
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
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with mild to moderate vascular dementia.
Part B Prerequisite	No

MEPSEVII

Products Affected

- Mepsevii

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient beta-glucuronidase activity in leukocytes, fibroblasts, or serum OR has a molecular genetic test demonstrating glucuronidase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

METHYLERGONOVINE

Products Affected

- methylergonovine oral

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MODAFINIL/ARMODAFINIL

Products Affected

- armodafinil
- modafinil oral tablet 100 mg, 200 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	Excessive daytime sleepiness associated with narcolepsy-prescribed by or in consultation with a sleep specialist physician or neurologist
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD) - approve if patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome-approve. Excessive daytime sleepiness associated with Narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Excessive daytime sleepiness (EDS) associated with myotonic dystrophy (modafinil only). Adjunctive/augmentation for treatment of depression in adults (modafinil only).
Part B Prerequisite	No

MONJUVI

Products Affected

- Monjuvi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-Cell Lymphoma - Approve if the patient meets the following criteria: Patient has been treated with at least one prior chemotherapy regimen AND the patient is not eligible for autologous stem cell transplant AND Monjuvi will be used in combination with Revlimid (lenalidomide) OR Patient has already received 12 cycles of Monjuvi. B-cell lymphoma-Approve if the patient meets the following criteria: Patient has been treated with at least one prior chemotherapy regimen AND the patient is not eligible for autologous stem cell transplant AND Monjuvi will be used in combination with Revlimid (lenalidomide) OR Patient has already received 12 cycles of Monjuvi.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MYALEPT

Products Affected

- Myalept

PA Criteria	Criteria Details
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 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NAGLAZYME

Products Affected

- Naglazyme

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine 4-sulfatase (arylsulfatase B) activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating arylsulfatase B gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NATPARA

Products Affected

- Natpara

PA Criteria	Criteria Details
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	1 year
Other Criteria	Chronic hypoparathyroidism, initial therapy - approve if before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician. Chronic hypoparathyroidism, continuing therapy - approve if during Natpara therapy, the patient's 25-hydroxyvitamin D stores are sufficient per the prescribing physician, AND the patient is responding to Natpara therapy, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NAYZILAM

Products Affected

- Nayzilam

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other medications used at the same time
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NERLYNX

Products Affected

- Nerlynx

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Stage of cancer, HER2 status, previous or current medications tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Adjuvant tx-Approve for 1 year (total), advanced or metastatic disease-3yrs
Other Criteria	Breast cancer, adjuvant therapy - approve if the patient meets all of the following criteria: patient will not be using this medication in combination with HER2 antagonists, patient has HER2-positive breast cancer AND Patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has HER-2 positive breast cancer, Nerlynx will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NEXAVAR

Products Affected

- sorafenib

PA Criteria	Criteria Details
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: Gleevec (imatinib mesylate), Ayvakit (avapritinib), Sutent (sunitinib), Sprycel (dasatinib), Qinlock (ripretinib) or Stivarga (regorafenib). 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 Caprelsa (vandetanib) or Cometriq (cabozantinib). AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test. Renal cell carcinoma (RCC)-approve if the patient has relapsed or Stage IV clear cell histology and the patient has tried at least one prior systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and Nexavar (sorafenib) is used in combination with topotecan.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Osteosarcoma, angiosarcoma, desmoids tumors (aggressive fibromatosis), gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, Chordoma with recurrent disease, solitary fibrous tumor and hemangiopericytoma, ovarian, fallopian tube, primary peritoneal cancer

PA Criteria	Criteria Details
Part B Prerequisite	No

NEXLETOL

Products Affected

- Nexletol

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	Heterozygous Familial Hypercholesterolemia (HeFH)-approve if pt meets one of the following: patient has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL (prior to treatment with antihyperlipidemic agents) OR patient has genetic confirmation of HeFH by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 or low-density lipoprotein receptor adaptor protein 1 gene OR patient has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds (a or b): a) The prescriber used the Dutch Lipid Network criteria and the patient has a score greater than 5 OR b) The prescriber used the Simon Broome criteria and the patient met the threshold for definite or possible familial hypercholesterolemia AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly and LDL-C remains greater than or equal to 70 mg/dL unless the patient 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 rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt meets all of the following: Pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA,

PA Criteria	Criteria Details
	PAD, undergone a coronary or other arterial revascularization procedure, AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly and LDL-C remains greater than or equal to 70 mg/dL unless the patient 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 rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NEXLIZET

Products Affected

- Nexlizet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	Heterozygous Familial Hypercholesterolemia (HeFH) -approve if pt meets one of the following: has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL (prior to treatment with antihyperlipidemic agents) OR has genetic confirmation of HeFH by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 or low-density lipoprotein receptor adaptor protein 1 gene OR has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds (a or b): a) The prescriber used the Dutch Lipid Network criteria and the patient has a score greater than 5 OR b) The prescriber used the Simon Broome criteria and the patient met the threshold for definite or possible familial hypercholesterolemia AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL-C remains greater than or equal to 70 mg/dL unless the patient 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 rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt meets all of the following: Pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other

PA Criteria	Criteria Details
	arterial revascularization procedure, AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL-C remains greater than or equal to 70 mg/dL unless the patient 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 rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NILUTAMIDE

Products Affected

- nilutamide

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Prostate cancer-approve if nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NINLARO

Products Affected

- Ninlaro

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	MM - be used in combination with Revlimid and dexamethasone OR pt had received at least ONE previous therapy for multiple myeloma OR the agent will be used following autologous stem cell transplantation (ASCT). Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma-approve if used in combination with a rituximab product and dexamethasone(Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma
Part B Prerequisite	Yes

NITISINONE

Products Affected

- nitisinone

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant therapy with nitisinone products
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	1 year
Other Criteria	HereditaryTyrosinemia, Type 1-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the FAH gene OR elevated levels of succinylacetone.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NIVESTYM

Products Affected

- Nivestym

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
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. Radiation-expertise in acute radiation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6mo.HIV/AIDS-4mo.MDS-3mo.PBPC,Drug induce A/N,AA,ALL,BMT-3mo. Radi-1mo. Other=12mo.
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 percent 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 percent 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), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) 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

PA Criteria	Criteria Details
	[absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	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). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome).
Part B Prerequisite	No

NON-INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- Androderm
- testosterone transdermal gel
- testosterone transdermal gel in metered-dose pump 10 mg/0.5 gram /actuation, 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %)
- testosterone 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)
- testosterone transdermal solution in metered pump w/app

PA Criteria	Criteria Details
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	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
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 (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as

PA Criteria	Criteria Details
	an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)
Part B Prerequisite	No

NORTHERA

Products Affected

- droxidopa

PA Criteria	Criteria Details
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
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUBEQA

Products Affected

- Nubeqa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy or if the medication is used concurrently with Firmagon. Prostate cancer-metastatic, castration sensitive-approve if (A and B): A) the medication is used in combination with docetaxel or patient has completed docetaxel therapy, and B) the medication will be used in combination with a GnRH agonist or in combination with Firmagon or if the patient had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUCALA

Products Affected

- Nucala subcutaneous auto-injector
- Nucala subcutaneous recon soln
- Nucala subcutaneous syringe 100 mg/mL, 40 mg/0.4 mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody.
Required Medical Information	N/A
Age Restrictions	Asthma-6 years of age and older. EGPA/Polyps-18 years of age and older. HES-12 years 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. HES-prescribed by or in consultation with an allergist, immunologist, hematologist, pulmonologist or rheumatologist. Polyps-prescribed by or in consult with allergist, immunologist or Otolaryngologist.
Coverage Duration	Initial-Asthma/EGPA/polyps-6 months, HES-8 months. 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 wks (prior to tx with any anti-IL-5) AND has received combo tx w/inhaled corticosteroid AND at least 1 additional asthma controller/maintenance med AND pt's asthma cont to be uncontrolled, or was uncontrolled prior to starting any anti-IL tx as defined by 1 of following-pt experi 2 or more asthma exacer req tx w/systemic corticosteroids in prev yr, pt experienced 1 or more asthma exacer requiring hospitalization or ED visit in the prev yr, pt has a FEV1 less than 80 percent predicted, Pt has FEV1/FVC less than 0.80, or Pt's asthma worsens upon taper of oral corticosteroid therapy.NOTE:An exception to requirement for trial of 1 additional asthma controller/maintenance med can be made if pt has already received anti-IL-5 tx used concomitantly with an ICS.Cont-pt responded to Nucala tx as determined by the prescribing physician AND Pt cont to receive tx with an inhaled corticosteroid. EGPA initial-approve if pt has active, non-severe disease, has/had a blood eosinophil level of greater than or equal to 150

PA Criteria	Criteria Details
	cells per microliter within the previous 6 wks or within 6 wks prior to tx w/any anti-IL-5 tx. Cont-pt responded to Nucala tx as determined by the prescribing physician.HES initial-pt has had hypereosinophilic synd for greater than or equal to 6 months AND has FIP1L1-PDGFRalpha-negative dis AND pt does NOT have identifiable non-hematologic secondary cause of hypereosinophilic synd AND prior to initiating tx with any anti-IL-5 tx, pt has/had a blood eosinophil level of greater than or equal to 1,000 cells per microliter. Cont-approve if the patient has responded to Nucala tx. Nasal polyps, initial-approve if pt meets ALL of the following criteria(A, B, C and D):A) pt has chronic rhinosinusitis w/nasal polyposis as evidenced by direct examination, endoscopy, or sinus CT scan AND B)pt experienced 2 or more of the following sympt for at least 6 months:nasal congest/obstruct/discharge, and/or reduction/loss of smell AND C)pt meets BOTH of the following (a and b): a)Pt has received tx with intranasal corticosteroid AND b)Pt will continue to receive tx with intranasal corticosteroid concomitantly with Nucala AND D)pt meets 1 of the following (a, b or c): a)Pt has received at least 1 course of tx with a systemic corticosteroid for 5 days or more within the previous 2 years, OR b)Pt has a contraindication to systemic corticosteroid tx, OR c)Pt had prior surgery for nasal polyps.Cont-approve if the pt has received at least 6 months of therapy, continues to receive tx with an intranasal corticosteroid and has responded to tx.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUEDEXTA

Products Affected

- Nuedexta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUPLAZID

Products Affected

- Nuplazid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NURTEC

Products Affected

- Nurtec ODT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine, Acute treatment-approve. Preventive treatment of episodic migraine-approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication) and 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. A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try two standard prophylactic pharmacologic therapies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NYVEPRIA

Products Affected

- Nyvepria

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-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 percent 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 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy

PA Criteria	Criteria Details
Part B Prerequisite	No

OCALIVA

Products Affected

- Ocaliva

PA Criteria	Criteria Details
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)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)
Coverage Duration	6 months initial, 1 year 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) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative 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)).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OCREVUS

Products Affected

- Ocrevus

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other Disease-Modifying Agents used for MS
Required Medical Information	N/A
Age Restrictions	18 years of age and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with, a physician who specializes in the treatment of MS and/or a neurologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	Relapsing forms of MS-Patients new to therapy-approve if the patient had a trial with generic dimethyl fumarate prior to approval of Ocrevus. (Note: Prior treatment with Tecfidera, Bafiertam or Vumerity also counts. Also, a patient who has previously tried a glatiramer product (Copaxone, Glatopa, generic) or Lemtrada, Tysabri or Kesimpta can bypass the requirement of a trial of generic dimethyl fumarate). Continuation-approve if the patient has responded to therapy. Primary progressive MS-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OCTREOTIDE INJECTABLE

Products Affected

- octreotide acetate

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-presc/consult with oncologist
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. Patient has had an inadequate response to surgery and/or radiotherapy OR ii. Patient is NOT an appropriate candidate for surgery and/or radiotherapy OR iii. Patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND Patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma
Part B Prerequisite	No

ODOMZO

Products Affected

- Odomzo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	BCC - Must not have had disease progression while on Erivedge (vismodegib).
Age Restrictions	18 years and older
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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Metastatic BCC
Part B Prerequisite	No

OFEV

Products Affected

- Ofev

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.
Coverage Duration	1 year
Other Criteria	IPF - must have FVC greater than or equal to 40 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. Interstitial lung disease associated with systemic sclerosis-approve if the FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography. Chronic fibrosing interstitial lung disease-approve if the forced vital capacity is greater than or equal to 45 percent of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10 percent of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OJJAARA

Products Affected

- Ojjaara

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Myelofibrosis-approve if the patient has intermediate-risk or high-risk disease and the patient has anemia, defined as hemoglobin less than 10g/dL.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ONUREG

Products Affected

- Onureg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	AML - Approve if the patient meets the following criteria (both A and B): A)Following intensive induction chemotherapy, the patient achieves one of the following according to the prescriber (i or ii): i. First complete remission OR ii. First complete remission with incomplete blood count recovery AND B) Patient is not able to complete intensive curative therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OPDIVO

Products Affected

- Opdivo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	colon/rectal-12 years and older, pediatric hodgkin lymphoma-less than 18 years old, All other (except gestational trophoblastic)-18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Adjuvant treatment of melanoma-approve up to 1 year total, all other dx-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	anal carcinoma, cervical carcinoma, endometrial carcinoma, extranodal NK/T-Cell Lymphoma, gestational trophoblastic neoplasia, merkel cell carcinoma, neuroendocrine tumors, pediatric hodgkin lymphoma, small bowel adenocarcinoma, small cell lung cancer, vulvar cancer, ampullary adenocarcinoma, bone cancer, diffuse high-grade gliomas, Kaposi sarcoma, primary mediastinal large B-cell lymphoma
Part B Prerequisite	No

OPDUALAG

Products Affected

- Opdualag

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Melanoma-approve if the patient is greater than or equal to 40 kg and if the patient has unresectable or metastatic disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OPSUMIT

Products Affected

- Opsumit

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	PAH WHO group, right heart catheterization results, WHO functional status, previous drugs tried
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 are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORENCIA

Products Affected

- Orencia (with maltose)
- Orencia ClickJect
- Orencia subcutaneous syringe 125 mg/mL, 50 mg/0.4 mL, 87.5 mg/0.7 mL

PA Criteria	Criteria Details
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	Initial therapy only-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	1 year
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). PsA, initial -approve. Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], initial - approve if the patient has tried one other agent for this condition or the patient will be starting on Orencia concurrently with methotrexate, sulfasalazine or leflunomide or the patient has an absolute contraindication to methotrexate, sulfasalazine or leflunomide or the patient has aggressive disease as determined by the prescribing physician. Cont tx - responded to therapy as per the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORGOVYX

Products Affected

- Orgovyx

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Prostate Cancer-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORKAMBI

Products Affected

- Orkambi oral granules in packet
- Orkambi oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Kalydeco, Trikafta or Symdeko.
Required Medical Information	N/A
Age Restrictions	1 year 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 - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORLADEYO

Products Affected

- Orladeyo

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant Use with Other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda, Takhzyro).
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders. (initial and continuation)
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Continuation-According to the prescriber the patient has had a favorable clinical response since initiating Orladeyo prophylactic therapy compared with baseline.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORSERDU

Products Affected

- Orserdu oral tablet 345 mg, 86 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast cancer in postmenopausal women or Men-approve if the patient meets the following criteria (A, B, C, D, and E): A) Patient has recurrent or metastatic disease, AND B) Patient has estrogen receptor positive (ER+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has estrogen receptor 1 gene (ESR1)-mutated disease, AND E) Patient has tried at least one endocrine therapy. Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OTEZLA

Products Affected

- Otezla
- Otezla Starter oral tablets,dose pack 10 mg (4)-20 mg (4)-30 mg (47), 10 mg (4)-20 mg (4)-30 mg(19)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous drugs tried
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	All dx-initial only-PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist. Behcet's-prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	1 year
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. Behcet's-patient has oral ulcers or other mucocutaneous involvement AND patient has tried at least ONE other systemic therapy. PsA/PP/Behcet's cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OXERVATE

Products Affected

- Oxervate

PA Criteria	Criteria Details
Exclusion Criteria	Treatment duration greater than 16 weeks per affected eye(s)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an ophthalmologist or an optometrist.
Coverage Duration	Initial-8 weeks, continuation-approve for an additional 8 weeks
Other Criteria	Patients who have already received Oxervate-approve if the patient has previously received less than or equal to 8 weeks of treatment per affected eye(s) and the patient has a recurrence of neurotrophic keratitis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PADCEV

Products Affected

- Padcev

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Urothelial carcinoma-approve if the patient has locally advanced or metastatic disease and has tried at least one other systemic therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PANRETIN

Products Affected

- Panretin

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist
Coverage Duration	1 year
Other Criteria	Kaposi Sarcoma-approve if the patient is not receiving systemic therapy for Kaposi Sarcoma.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PEMAZYRE

Products Affected

- Pemazyre

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years
Other Criteria	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease and the tumor has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the cancer has fibroblast growth factor receptor 1 (FGFR1) rearrangement, as detected by an approved test and the cancer is in chronic phase or blast phase.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PENICILLAMINE

Products Affected

- penicillamine oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Wilson's Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PHENYLBUTYRATE

Products Affected

- Ravicti
- sodium phenylbutyrate

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Ravicti and Buphenyl
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval
Other Criteria	Urea cycle disorders-approve if genetic testing confirmed a mutation resulting in a urea cycle disorder or if the patient has hyperammonemia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PHEOCHROMOCYTOMA

Products Affected

- metyrosine

PA Criteria	Criteria Details
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 and continuation therapy for metyrosine)
Coverage Duration	Authorization will be for 1 year
Other Criteria	If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin). If the requested drug is metyrosine for continuation therapy, approve if the patient is currently receiving metyrosine or has received metyrosine in the past.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

- Alyq
- sildenafil (Pulmonary Arterial Hypertension) intravenous solution 10 mg/12.5 mL
- sildenafil (Pulmonary Arterial Hypertension) oral tablet 20 mg
- tadalafil (pulmonary arterial hypertension) oral tablet 20 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, right heart cath results
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 1 year.
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PIQRAY

Products Affected

- Piqray

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, E and F): A) The patient is a postmenopausal female or a male or premenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) analog or has had surgical bilateral oophorectomy or ovarian irradiation AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene) AND F) Piqray will be used in combination with fulvestrant injection.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Treatment of breast cancer in premenopausal women
Part B Prerequisite	No

PLEGRIDY

Products Affected

- Plegridy intramuscular
- 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
Exclusion Criteria	Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
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	Cont tx-approve if the patient has been established on Plegridy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

POLIVY

Products Affected

- Polivy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	6 months
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-cell lymphoma/B-Cell Lymphoma-Approve if the patient has been treated with at least one prior chemotherapy regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	B-Cell Lymphoma
Part B Prerequisite	No

POMALYST

Products Affected

- Pomalyst

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Kaposi Sarcoma/MM-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years
Other Criteria	CNS Lymphoma-approve if the patient has relapsed or refractory disease. Kaposi Sarcoma-Approve if the patient meets one of the following (i or ii): i. patient is Human Immunodeficiency Virus (HIV)-negative OR ii. patient meets both of the following (a and b): a) The patient is Human Immunodeficiency Virus (HIV)-positive AND b) The patient continues to receive highly active antiretroviral therapy (HAART). MM-approve if the patient has received at least one other Revlimid (lenalidomide tablets)-containing regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma
Part B Prerequisite	No

POSACONAZOLE (ORAL)

Products Affected

- posaconazole oral tablet,delayed release (DR/EC)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Aspergillus/Candida prophy, mucormycosis-6 mo, all others-3 months
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	mucomycosis - maintenance, fusariosis, invasive - treatment fungal infections (systemic) in patients with human immunodeficiency virus (HIV) infections (e.g., histoplasmosis, coccidioidomycosis) - treatment.
Part B Prerequisite	No

POTELIGEO

Products Affected

- Poteligeo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Mycosis fungoides/Sezary-prescribed by, or in consultation with an oncologist or dermatologist. ATLL-prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Mycosis Fungoides/Sezary Syndrome-Approve. ATLL-patient has relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adults with T-cell leukemia/lymphoma (ATLL)
Part B Prerequisite	No

PROLIA

Products Affected

- Prolia

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

PA Criteria	Criteria Details
	exemestane). Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PROMACTA

Products Affected

- Promacta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts.
Age Restrictions	N/A
Prescriber Restrictions	Immune Thrombocytopenia or Aplastic Anemia, approve if prescribed by, or after consultation with, a hematologist (initial therapy). Thrombocytopenia in pt with chronic Hep C, approve if prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease (initial therapy). MDS-presc or after consult with heme/onc (initial therapy).
Coverage Duration	Immune Thrombo/MDS initial-3 mo, cont 1yr, AA-initial-4 mo, cont-1 yr, Thrombo/Hep C-1 yr
Other Criteria	Thrombocytopenia in patients with immune thrombocytopenia, initial-approve if the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy or has undergone a splenectomy. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Treatment of thrombocytopenia in patients with Chronic Hepatitis C initial-approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND to allow for initiation of antiviral therapy if the patient has low platelet counts at baseline (eg, less than 75,000 microliters). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000 microliters) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate moefetil, sirolimus) OR patient will be using Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk

PA Criteria	Criteria Details
	for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Thrombocytopenia in Myelodysplastic Syndrome (MDS)
Part B Prerequisite	No

PYRIMETHAMINE

Products Affected

- pyrimethamine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Patient's immune status (Toxoplasma gondii Encephalitis, chronic maintenance and prophylaxis, primary)
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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis
Part B Prerequisite	No

QINLOCK

Products Affected

- Qinlock

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years
Other Criteria	Gastrointestinal stromal tumor (GIST), advanced-approve if, the patient has two of the following imatinib, sunitinib, Sprycel or Stivarga OR if the patient has tried Ayvakit and Sprycel. Melanoma, cutaneous-approve if the patient has metastatic or unresectable disease, AND the patient has an activating KIT mutation, AND the patient has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Melanoma, cutaneous
Part B Prerequisite	No

RADICAVA

Products Affected

- Radicava

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	ALSFRS-R score, FVC %, time elapsed since diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS (initial and continuation).
Coverage Duration	Initial, 6 months. Continuation, 6 months
Other Criteria	ALS, initial therapy - approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, based on the application of the El Escorial or the revised Airlie house diagnostic criteria AND 2. Patient has a score of two points or more on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. Patient has a percent predicted FVC greater than or equal to 80% (ie, has normal respiratory function), AND 4. Patient has been diagnosed with ALS for less than or equal to 2 years. 5. Patient has received or is currently receiving riluzole tablets. Note-a trial of Tiglutik or Exservan would also count. ALS, continuation therapy - approve if, according to the prescribing physician, the patient continues to benefit from therapy AND the patient is not requiring invasive ventilation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RECLAST

Products Affected

- zoledronic acid-mannitol-water intravenous piggyback 5 mg/100 mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Medications for Osteoporosis (e.g., other bisphosphonates, Evenity, Prolia, Forteo/Bonsity, Tymlos, calcitonin nasal spray)
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Paget's 1 month. Others 12 months.
Other Criteria	Tx of osteo in post menopausal pt or osteo in men (a man defined as an individual with biological traits of man, regardless of the individual's gender identity/gender expression), must meet ONE of the following: pt had inadequate response after 12 mo (eg,ongoing and sign loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or pt experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot swallow or has difficulty swallowing or pt cannot remain in upright position post oral bisphos admin or pt has pre-existing GI condition (eg, pt with esophageal lesions/ulcers, or abnormal of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt had an osteo fracture or a fragility fracture OR pt has tried IV Reclast (zoledronic acid). Tx of PMO may have also tried IV Boniva (ibandronate) for approval. Prevent or tx of GIO, approve if: pt is initiating or cont therapy with systemic glucocorticoids, AND had an inadequate response after 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had an osteo fracture or fragility fracture while on therapy or pt experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot

PA Criteria	Criteria Details
	swallow or has difficulty swallowing or pt cannot remain in an upright position post oral bisphos administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), or has tried Reclast OR patient had an osteo fracture or a fragility fracture. Tx of Paget's disease, approve if pt has elevations in serum alkaline phos of two times higher than the upper limit of the age-specific normal reference range, OR pt is symptomatic (eg,bone pain, hearing loss, osteoarthritis), OR pt is at risk for complications from their disease (eg,immobilization, bone deformity, fractures, nerve compression syndrome). Prevent of PMO - meets 1 of the following had inadequate response after trial duration of 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or patient experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphos admin or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions/ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried Reclast or the patient has had an osteo fracture or fragility fracture.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REMICADE

Products Affected

- Remicade

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medication, previous medications tried
Age Restrictions	CD and UC, Pts aged 6 years or more (initial therapy). PP-18 years and older (initial therapy)
Prescriber Restrictions	All dx-initial therapy only-Prescribed by or in consult w/RA/AS/Still's/JIA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's-rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarcoidosis-pulmonol, ophthalmol, or dermatol.
Coverage Duration	FDAind ini-3 mo,cont1yr,GVHD ini-1 mo,cont-3 mo,Pyo Gang-ini4 mo,cont1 yr,others-ini 3mo,cont-12 mo
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). CD approve if the pt has tried corticosteroid (CS) or if CSs contraindicated or if currently on CS or if the patient has tried one other conventional systemic therapy for CD OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had ileocolonic resection.Note-a previous trial of a biologic also counts as a trial of one other agent for CD. Ulcerative colitis (UC).Tried one systemic agent or was intolerant to one of these agents OR the patient has pouchitis AND has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Note-a previous trial of a biologic also counts as a trial of one systemic agent for UC. Behcet's.Pt has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa). NOTE: An exception to the requirement for a trial of one conventional therapy can be made if the

PA Criteria	Criteria Details
	patient has already had a trial of at least one tumor necrosis factor for Behcet's disease. These patients who have already tried a biologic for Behcet's disease are not required to "step back" and try a conventional therapy) OR has ophthalmic manifestations. SD.Tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant.UV.Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab. Sarcoidosis.Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG).Tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Hidradenitis suppurativa (HS).Tried 1 tx (eg, intralesional/oral CS, systemic antibiotic, isotretinoin).GVHD.Tried one conventional systemic treatment (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.). JIA (regardless of type of onset) approve if pt has tried 1 other agent for this condition (eg, MTX, sulfasalazine, or leflunomide, an NSAID, or one biologic DMARD [eg, Humira, Orencia, Enbrel, Kineret, Actemra]) or the pt has aggressive disease. PP- approve if the patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant or the patient has a contraindication to methotrexate (MTX), as determined by the prescriber.Note-a previous trial of a biologic also counts as a trial of a systemic agent. cont tx - approve if patient has had a response, as determined by the prescriber.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Juvenile Idiopathic Arthritis (JIA). Sarcoidosis
Part B Prerequisite	No

REMODULIN

Products Affected

- treprostinil sodium

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	PAH WHO Group 1, prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation).
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Pulmonary Arterial Hypertension (PAH) [World Health Organization (WHO) Group 1], Initial Therapy-Approve if the patient meets all of the following criteria (i, ii, iii, and iv): i. Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH), AND ii. Patient meets the following criteria (a and b): a) Patient has had a right heart catheterization, AND b) Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH, AND iii. Patient meets ONE of the following criteria (a or b): a) Patient is in Functional Class III or IV, OR b) Patient is in Functional Class II and meets ONE of the following criteria [(1) or (2)]: (1) Patient has tried or is currently receiving one oral agent for PAH, OR (2) Patient has tried one inhaled or parenteral prostacyclin product for PAH, AND iv. Patient with idiopathic PAH must meet ONE of the following criteria (a, b, c, d, or e): a) Patient meets both of the following criteria [(1) and (2)]: (1) the patient has had an acute response to vasodilator testing that occurred during the right heart catheterization, AND (2) Patient has tried one calcium channel blocker (CCB) therapy, OR b) According to the prescriber, the patient did not have an acute response to vasodilator testing, OR c) According to the prescriber, the patient cannot undergo a vasodilator test, OR d) Patient cannot take CCB therapy, OR e) Patient has tried one CCB. Continuation-Approve if the patient meets ALL of the following

PA Criteria	Criteria Details
	conditions (a and b): a) Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH), AND b) Patient meets the following criteria [(1) and (2)]: (1) Patient has had a right heart catheterization, AND (2) Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REPATHA

Products Affected

- Repatha
- Repatha Pushtronex
- Repatha SureClick

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Leqvio or Praluent.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 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 1 year
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 rosuvastatin 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 rosuvastatin 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 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 (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or

PA Criteria	Criteria Details
	higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the patient has 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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RETEVMO

Products Affected

- Retevmo oral capsule 40 mg, 80 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Medullary Thyroid Cancer/Thyroid Cancer-12 years and older, all others 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has metastatic disease AND the tumor is RET fusion-positive. Medullary Thyroid Cancer-approve if the patient has advanced or metastatic RET-mutant disease and the disease requires treatment with systemic therapy.Thyroid Cancer-approve if the patient has advanced or metastatic RET fusion positive disease, the disease is radioactive iodine-refractory (if radioactive iodine is appropriate) and the disease requires treatment with systemic therapy. Anaplastic thyroid cancer-approve if the patient has RET fusion-positive anaplastic thyroid carcinoma. Solid tumors-approve if the patient has recurrent, advanced or metastatic disease and the tumor is rearranged during transfection (RET) fusion-positive.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anaplastic thyroid carcinoma
Part B Prerequisite	No

REVCOVI

Products Affected

- Revcovi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab values, genetic tests (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with, an immunologist, hematologist/oncologist, or physician that specializes in ADA-SCID or related disorders.
Coverage Duration	12 months
Other Criteria	ADA-SCID - approve if the patient had absent or very low (less than 1% of normal) ADA catalytic activity at baseline (i.e., prior to initiating enzyme replacement therapy) OR if the patient had molecular genetic testing confirming bi-allelic mutations in the ADA gene
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REVLIMID

Products Affected

- lenalidomide
- Revlimid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and previous therapies or drug regimens tried.
Age Restrictions	18 years and older (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma)
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Follicular lymphoma-approve if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least on prior therapy. MCL-approve -if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least one other therapy or therapeutic regimen. Multiple myeloma-approve. 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]). B-cell-lymphoma (other)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia and the pt has serum erythropoietin levels greater than or equal to 500 mU/mL or according to the prescriber the patient has anemia, has serum erythropoietin levels less than 500 mU/mL and patient has experienced no response or loss of response to erythropoietic stimulating agents. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried at least one other therapy or regimen. CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-

PA Criteria	Criteria Details
	approve if the patient has tried at least one other therapy or therapeutic regimen. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide (brand or generic) is used in combination with dexamethasone.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Off label uses for Revlimid and lenalidomide include-Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system Lymphoma,Kaposi's sarcoma. Off label uses for lenalidomide include-follicular lymphoma, marginal zone lymphoma and multiple myeloma following autologous hematopoietic stem cell transplantation.
Part B Prerequisite	No

REZLIDHIA

Products Affected

- Rezlidhia

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Acute myeloid leukemia-approve if the patient has relapsed or refractory disease and the patient has isocitrate dehydrogenase-1 (IDH1) mutation positive disease as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RILUZOLE

Products Affected

- riluzole

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RINVOQ

Products Affected

- Rinvoq oral tablet extended release 24 hr
  15 mg, 30 mg, 45 mg

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants. Concurrent use with an anti-interleukin monoclonal antibody, Concurrent use with other janus kinase inhibitors, or concurrent use with Xolair.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	PsA/RA/UC/AS/CD-18 years and older (initial therapy), AD-12 years and older (initial therapy)
Prescriber Restrictions	RA/AS/Non-Radiographic Spondy, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or derm. UC/CD-prescribed by or in consultation with a gastroenterologist.
Coverage Duration	1 year
Other Criteria	RA/PsA/UC/AS/CD initial-approve if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AD-approve if the patient has had a 3 month trial of at least one traditional systmic therapy or has tried at least one traditional systemic therapy but was unable to tolerate a 3 month trial. Note: Examples of traditional systemic therapies include methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis. Non-Radiographic Axial Spondyloarthritis-approve if the patient has objective signs of inflammation defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroiliitis reported on MRI and patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3- month

PA Criteria	Criteria Details
	trial. Continuation Therapy - Patient must have responded, as determined by the prescriber
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ROZLYTREK

Products Affected

- Rozlytrek oral capsule 100 mg, 200 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Solid Tumors-12 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Solid Tumors-Approve if the patient's tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RUBRACA

Products Affected

- Rubraca

PA Criteria	Criteria Details
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	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3years
Other Criteria	Ovarian, Fallopian Tube or Primary Peritoneal Cancer-treatment - Approve 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. Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient is in complete or partial response after at least two platinum-based chemotherapy regimens. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy AND D) The patient meets one of the following criteria (i or ii): i. The patient has been previously treated with at least one taxane-based chemotherapy OR ii. The patient is not a candidate or is intolerant to taxane-based chemotherapy. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Uterine Leiomyosarcoma, treatment of patients with deleterious BRCA mutation associated advanced ovarian cancer who have been treated with two or more chemotherapies
Part B Prerequisite	No

RUFINAMIDE

Products Affected

- rufinamide

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Patients 1 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Initial therapy-approve if rufinamide is being used for adjunctive treatment. Continuation-approve if the patient is responding to therapy
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Treatment-Refractory Seizures/Epilepsy
Part B Prerequisite	No

RUXIENCE

Products Affected

- Ruxience

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RYBREVANT

Products Affected

- Rybrevant

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Non-Small Cell Lung Cancer (NSCLC) - approve if the has epidermal growth factor receptor exon 20 insertion mutations, as detected by an approved test AND has progressed on or following treatment with platinum-based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RYDAPT

Products Affected

- Rydapt

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For AML, FLT3 status
Age Restrictions	18 years and older
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. Myeloid or lymphoid Neoplasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid or lymphoid Neoplasms with eosinophilia
Part B Prerequisite	No

RYLAZE

Products Affected

- Rylaze

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Acute lymphoblastic leukemia/lymphoblastic lymphoma - approve if the patient has a systemic allergic reaction or anaphylaxis to a pegylated asparaginase product.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SANDOSTATIN LAR

Products Affected

- Sandostatin LAR Depot intramuscular suspension,extended rel recon

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous treatments/therapies
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly-prescr/consult w/endocrinologist. All neuroendocrine tumors-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist or neurosurgeon.Thymoma/Thymic carcinoma-prescr/consult w/oncologist
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if the patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas)-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pheochromocytoma/paraganglioma, Meningioma, Thymoma and thymic carcinoma
Part B Prerequisite	No

SAPROPTERIN

Products Affected

- sapropterin

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Palynziq
Required Medical Information	Diagnosis, Phe concentration
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	Initial - approve. Continuation (Note-if the patient has received less than 12 weeks of therapy or is restarting therapy with sapropterin should be reviewed under initial therapy) - approve if the patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescribing physician OR patient had a 20 percent or greater reduction in blood Phe concentration from baseline OR treatment with sapropterin has resulted in an increase in dietary phenylalanine tolerance.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SARCLISA

Products Affected

- Sarclisa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Multiple myeloma-approve if the requested medication will be used in combination with Pomalyst and dexamethasone and the patient has tried at least TWO prior regimens for multiple myeloma and a proteasome inhibitor was a component of at least one previous regimen and Revlimid was a component of at least one previous regimen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SCEMBLIX

Products Affected

- Scemblix oral tablet 20 mg, 40 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Chronic Myeloid Leukemia (CML)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i or ii): i. The chronic myeloid leukemia is T315I-positive, OR ii. Patient has tried at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia. Note: Examples of tyrosine kinase inhibitors include imatinib tablets, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), Sprycel (dasatinib tablets), and Tasigna (nilotinib capsules). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has an ABL1 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid Neoplasms with Eosinophilia
Part B Prerequisite	No

SENSIPAR

Products Affected

- cinacalcet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Hypercalcemia d/t parathyroid CA-prescr/consult w/onco or endo.Hypercalcemia w/primary hyperparathyroidism-prescr/consult w/nephro or endo. Hyperparathyroidism in post-renal transplant-prescr/consult w/transplant physician/nephro/endo.
Coverage Duration	12 months
Other Criteria	Hypercalcemia due to parathyroid carcinoma-approve. Hypercalcemia in patients with primary hyperparathyroidism-approve if the patient has failed or is unable to undergo a parathyroidectomy due to a contraindication. Secondary Hyperparathyroidism in patients with chronic kidney disease on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundles payment benefit). Hyperparathyroidism in Post-Renal Transplant Patients-approve if the baseline (prior to starting cinacalcet therapy) calcium and intact parathyroid hormone (iPTH) levels are above the normal range, as defined by the laboratory reference values.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	hyperparathyroidism in post-renal transplant patients
Part B Prerequisite	No

SIGNIFOR

Products Affected

- Signifor

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy)
Coverage Duration	Cushing's disease/syndrome-Initial therapy - 4 months, Continuation therapy - 1 year.
Other Criteria	Cushing's disease, initial therapy - approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushing's disease, continuation therapy - approve if the patient has already been started on Signifor/Signifor LAR and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SIRTURO

Products Affected

- Sirturo

PA Criteria	Criteria Details
Exclusion Criteria	Patients weighing less than 15 kg
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	Patients 5 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with an infectious diseases specialist
Coverage Duration	9 months
Other Criteria	Tuberculosis (Pulmonary)-Approve if the patient has multidrug-resistant tuberculosis and the requested medication is prescribed as part of a combination regimen with other anti-tuberculosis agents
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SKYRIZI

Products Affected

- Skyrizi intravenous
- Skyrizi subcutaneous pen injector
- Skyrizi subcutaneous syringe 150 mg/mL
- Skyrizi subcutaneous wearable injector 180 mg/1.2 mL (150 mg/mL), 360 mg/2.4 mL (150 mg/mL)

PA Criteria	Criteria Details
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 (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy), PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD-presc/consult-gastro
Coverage Duration	1 year
Other Criteria	PP-Initial Therapy-The patient meets ONE of the following conditions (a or b): a) The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant. NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g., an adalimumab product [Humira], a certolizumab pegol product [Cimzia], an etanercept product [Enbrel, Erelzi], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Stelara [ustekinumab SC injection], Taltz [ixekizumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional systemic agent for psoriasis)b) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician.Continuation Therapy - Patient must have responded, as determined by the prescriber. Psoriatic arthritis (initial)-approve. Continuation-patient must have responded as determined by the prescriber.

PA Criteria	Criteria Details
	CD, initial-approve if the patient has tried or is currently taking crticosteroids, or corticosteroids are contraindicated or if the patient has tried one other conventional systemic therapy for CD (Please note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for Crohn's disease.) or if the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas or if the patient had ileocolonic resection (to reduce the chance of CD recurrence). Patients must be receiving an induction dosing with Skyrizi IV within 3 month of initiating therapy with Skyrizi subcutaneous. Continuation-patient must have responded as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SOLARAZE

Products Affected

- diclofenac sodium topical gel 3 %

PA Criteria	Criteria Details
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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SOMATULINE

Products Affected

- Somatuline Depot

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous treatments/therapies
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescribed by or in consultation with an endo/onc/neuro.
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if the patient has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)-approve. Carcinoid Syndrome-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pheochromocytoma/paraganglioma
Part B Prerequisite	No

SOMAVERT

Products Affected

- Somavert

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. patient has had an inadequate response to surgery and/or radiotherapy OR ii. The patient is NOT an appropriate candidate for surgery and/or radiotherapy OR iii. The patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender for the reporting laboratory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SPRAVATO

Products Affected

- Spravato nasal spray,non-aerosol 56 mg (28 mg x 2), 84 mg (28 mg x 3)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by a psychiatrist
Coverage Duration	MDD w/Acute Suicidal Ideation or Behavior - 2 months, Treatment-Resistant Depression - 6 months
Other Criteria	Major Depressive Disorder with Acute Suicidal Ideation or Behavior: approve if the patient has major depressive disorder that is considered to be severe, AND if the patient is concomitantly receiving at least one oral antidepressant, AND the patient has no history of psychosis or has a history of psychosis but the prescriber believes that the benefits of Spravato outweigh the risks. Treatment-Resistant Depression: approve if the patient has demonstrated nonresponse (less than or equal to 25 percent improvement in depression symptoms or scores) to at least two different antidepressants, each from a different pharmacologic class and each antidepressant was used at therapeutic dosages for at least 6 weeks in the current episode of depression, AND patient is concomitantly receiving at least one oral antidepressant, AND the patient has no history of psychosis or has a history of psychosis but the prescriber believes that the benefits of Spravato outweigh the risks, AND patient's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

SPRYCEL

Products Affected

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

PA Criteria	Criteria Details
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. For melanoma, cutaneous- KIT mutation and previous therapies.
Age Restrictions	GIST/chondrocarcoma or chordoma/melanoma, cutaneous-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For CML, patient must have Ph-positive CML. For ALL, patient must have Ph-positive ALL. GIST - approve if the patient has tried imatinib or avapritinib. For melanoma, cutaneous - approve if patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	GIST, chondrosarcoma, chordoma, melanoma cutaneous
Part B Prerequisite	No

STELARA

Products Affected

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

PA Criteria	Criteria Details
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	18 years and older CD/UC (initial therapy). PP-6 years and older (initial therapy).
Prescriber Restrictions	Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy).
Coverage Duration	1 year
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 conventional systemic therapy for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumab, infliximab) OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). UC, initial therapy-approve SC if the patient received a single IV loading dose within 2 months of initiating therapy with Stelara SC. CD, initial therapy (only after receiving single IV loading dose within 2 months of initiating therapy with Stelara SC) - 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/UC cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy.PP initial - approve Stelara SC. CD, initial therapy - approve 3 months of the SC formulation if the

PA Criteria	Criteria Details
	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 conventional systemic therapy for CD OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). UC, initial therapy-approve SC if the patient received a single IV loading dose within 2 months of initiating therapy with Stelara SC. PP/PsA/CD/UC cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

STIVARGA

Products Affected

- Stivarga

PA Criteria	Criteria Details
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	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For GIST, patient must have previously been treated with imatinib or Ayvakit and sunitinib or Sprycel. For HCC, patient must have previously been treated with at least one systemic regimen. Soft tissue sarcoma, advanced or metastatic disease-approve if the patient has non-adipocytic sarcoma, angiosarcoma, or pleomorphic rhabdomyosarcoma.Osteosarcoma-approve if the patient has relapsed/refractory or metastatic disease and the patient has tried one systemic chemotherapy regimen. Colon and Rectal cancer-approve if the patient has advanced or metastatic disease, has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient's tumor or metastases are wild-type RAS, the patient has tried Erbitux or Vectibix. Glioblastoma-approve if the patient has recurrent disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Soft tissue Sarcoma, Osteosarcoma, Glioblastoma
Part B Prerequisite	No

STRENSIQ

Products Affected

- Strensiq

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	Disease onset-less than or equal to 18
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of hypophosphatasia or related disorders.
Coverage Duration	1 year
Other Criteria	Hypophosphatasia - Perinatal/Infantile- and Juvenile-Onset-Patient must meet both A and B for approval. A) Diagnosis is supported by one of the following (i, ii, or iii): i. Molecular genetic testing documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation OR ii. Low baseline serum alkaline phosphatase activity OR iii. An elevated level of a tissue non-specific alkaline phosphatase substrate (i.e., serum pyridoxal 5'-phosphate, serum or urinary inorganic pyrophosphate, urinary phosphoethanolamine) AND B) Patient meets one of the following (i or ii): i. Patient currently has, or has a history of clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, premature tooth loss, muscle weakness, poor feeding, failure to thrive, respiratory problems, Vitamin B6-dependent seizures) OR ii. Patient has a family history (parent or sibling) of hypophosphatasia without current clinical manifestations of hypophosphatasia
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SUCRAID

Products Affected

- Sucraid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient sucrase or isomaltase activity in duodenal or jejunal biopsy specimens OR patient has a sucrose hydrogen breath test OR has a molecular genetic test demonstrating sucrose-isomaltase mutation in saliva or blood.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SUTENT

Products Affected

- sunitinib malate

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Gastrointestinal stromal tumors (GIST), approve if the patient tried imatinib (Gleevec). Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried chemotherapy or radiation therapy. Renal Cell Carcinoma (RCC), clear cell or non-clear cell histology-approve if the patient is at high risk of recurrent clear cell RCC following nephrectomy and Sutent is used for adjuvant therapy or if the patient has relapsed or Stage IV disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	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.
Part B Prerequisite	No

SYMDEKO

Products Affected

- Symdeko

PA Criteria	Criteria Details
Exclusion Criteria	Patients with unknown CFTR gene mutations, Combination therapy with Orkambi, Kalydeco or Trikafta
Required Medical Information	Diagnosis, specific CFTR gene mutations
Age Restrictions	Six 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 be homozygous for the F508del mutation or have at least one mutation in the CFTR gene that is responsive to the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SYMLIN

Products Affected

- SymlinPen 120
- SymlinPen 60

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SYNAREL

Products Affected

- Synarel

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Endometriosis-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Central Precocious Puberty-12 months, Endometriosis-6 months
Other Criteria	Central precocious puberty-approve. Endometriosis-approve if the patient has tried one of the following, unless contraindicated, a contraceptive, an oral progesterone or a depo-medroxyprogesterone injection. Note: An exception to the requirement for a trial of the above therapies can be made if the patient has previously used a gonadotropin-releasing hormone (GnRH) agonist or antagonist for endometriosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TABRECTA

Products Affected

- Tabrecta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping or high-level MET amplification, as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer with high-level MET amplification.
Part B Prerequisite	No

TAFAMIDIS

Products Affected

- Vyndamax

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Onpattro or Tegsedi.Concurrent use of Vyndaqel and Vyndamax.
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis
Coverage Duration	1 year
Other Criteria	Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis-approve if the diagnosis was confirmed by one of the following (i, ii or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy), ii. Amyloid deposits are identified on cardiac biopsy OR iii. patient had genetic testing which, according to the prescriber, identified a TTR mutation AND Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAFINLAR

Products Affected

- Tafinlar oral capsule
- Tafinlar oral tablet for suspension

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tafinlar is being used. BRAF V600 mutations
Age Restrictions	6 years and older
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. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Mekinist. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i) adjuvant treatment of pilocytic astrocytoma OR pleomorphic xanthoastrocytoma OR ganglioglioma, OR ii) recurrent disease for one of the following: low-grade glioma OR anaplastic glioma OR glioblastoma, OR iii) melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following: multisystem disease OR pulmonary disease OR

PA Criteria	Criteria Details
	central nervous system lesions OR patient has Erdheim Chester disease AND patient has BRAF V600-mutation positive disease. Metastatic or solid tumors-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets) AND patient has no satisfactory alternative treatment options.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Differentiated Thyroid Cancer, Biliary tract cancer, central nervous system cancer, histiocytic neoplasm
Part B Prerequisite	No

TAGRISSO

Products Affected

- Tagrisso

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	NSCLC-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)- approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note-examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC-Post resection-approve if the patient has completely resected stage IB-IIIA disease and has received previous adjuvant chemotherapy or if the patient is ineligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TALTZ

Products Affected

- Taltz Autoinjector
- Taltz Autoinjector (2 Pack)
- Taltz Autoinjector (3 Pack)
- Taltz Syringe

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis, Previous medication use
Age Restrictions	PP-6 years and older (initial therapy), all other dx-18 years of age and older (initial therapy)
Prescriber Restrictions	All dx initial therapy only-PP-Prescribed by or in consultation with a dermatologist. PsA prescribed by or in consultation with a rheumatologist or a dermatologist. AS/spondylo -prescribed by or in consultation with a rheum.
Coverage Duration	1 year
Other Criteria	Initial Therapy - Plaque Psoriasis-approve if the patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant OR the patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic. PsA Initial-Approve. AS initial-approve. Non-Radiographic Axial Spondyloarthritis-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or sacroiliitis reported on magnetic resonance imaging. Continuation Therapy - approve if the patient has responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TALVEY

Products Affected

- Talvey

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Multiple myeloma-approve if per FDA approved labeling the patient has tried at least four systemic regimens and among the previous regimens tried, the patient has received at least one drug from each of the following classes: proteasome inhibitor, an immunomodulatory drug and an anti-CD38 monoclonal antibody.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TALZENNA

Products Affected

- Talzenna oral capsule 0.1 mg, 0.25 mg, 0.35 mg, 0.5 mg, 0.75 mg, 1 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Recurrent or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive disease. Prostate cancer - approve if the patient has metastatic castration resistant prostate cancer, AND is using this medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy AND the patient has homologous recombination repair (HRR) gene-mutated disease [Note: HRR gene mutations include ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C] AND the medication is used in combination with Xtandi (enzalutamide capsules and tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TARGRETIN TOPICAL

Products Affected

- bexarotene

PA Criteria	Criteria Details
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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TASIGNA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and melanoma, cutaneous, prior therapies tried. For melanoma, cutaneous, KIT mutation status.
Age Restrictions	ALL/GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For CML, patient must have Ph-positive CML. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafinib or ripretinib. For ALL, Approve if the patient has philadelphia chromosome-positive acute lymphoblastic leukemia. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement. Pigmented villonodular synovitis/tenosynovial giant cell tumor-approve if the patient has tried Turalio or cannot take Turalio, according to the prescriber. For melanoma, cutaneous - approve if the patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST), Pigmented villonodular synovitis/tenosynovial giant cell tumor, Myeloid/Lymphoid neoplasms with Eosinophilia, melanoma cutaneous.

PA Criteria	Criteria Details
Part B Prerequisite	No

TAZAROTENE

Products Affected

- tazarotene topical cream
- tazarotene topical gel

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic uses
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAZVERIK

Products Affected

- Tazverik

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Epitheliod Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if the patient has relapsed or refractory disease and according to the prescriber, there are no appropriate alternative therapies or the patient's tumor is positive for an EZH2 mutation and the patient has tried at least two prior systemic therapies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TECVAYLI

Products Affected

- Tecvayli

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. Multiple Myeloma-approve if the patient has tried at least four systemic regimens which must include at least one drug from each of the following classes: proteasome inhibitor, immunomodulatory drug and Anti-CD38 monoclonal antibody
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TEPMETKO

Products Affected

- Tepmetko

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	NSCLC-approve if the patient has metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutations or patient has high-level MET amplification, as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer with high-level MET amplification.
Part B Prerequisite	No

TERIPARATIDE

Products Affected

- teriparatide

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/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 CKD or has had an osteoporotic fracture or fragility fracture. Patients who

PA Criteria	Criteria Details
	have already taken teriparatide for 2 years - approve if the patient is at high risk for fracture.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TETRABENAZINE

Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
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	Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.
Part B Prerequisite	No

THALOMID

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	MM, myelofibrosis-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Myelofibrosis, approve if according to the prescriber the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/mL or if the patient has serum erythropoietin level less than 500 mU/mL and experienced no response or loss of response to erythropoietic stimulating agents. Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease. Castleman's disease-approve if the patient has multicentric Castleman's disease, and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi's Sarcoma, Castleman's Disease.
Part B Prerequisite	No

TIBSOVO

Products Affected

- Tibsovo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, IDH1 Status
Age Restrictions	All diagnoses (except chondrosarcoma)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive, as detected by an approved test. Cholangiocarcinoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and has been previously treated with at least one chemotherapy regimen (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan). Chondrosarcoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Central nervous system cancer-approve if the patient has recurrent or progressive disease, AND patient has World Health Organization (WHO) grade 2 or 3 oligodendroglioma, OR Patient has WHO grade 2 astrocytoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chondrosarcoma, Central nervous system cancer
Part B Prerequisite	Yes

TIVDAK

Products Affected

- Tivdak

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Cervical cancer-approve if the patient has tried at least one chemotherapy agent.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOBRAMYCIN (NEBULIZATION)

Products Affected

- tobramycin in 0.225 % NaCl
- tobramycin inhalation

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Bronchiectasis, Non-cystic fibrosis-18 years and older
Prescriber Restrictions	CF-prescr/consult w/pulm/phys specializes in tx of CF.Bronchiectasis, non CF-prescr/consult w/pulm
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Cystic fibrosis/Bronchiectasis, non-cystic fibrosis-approve if the patient has pseudomonas aeruginosa in the culture of the airway.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bronchiectasis, non-cystic fibrosis
Part B Prerequisite	No

TOLVAPTAN

Products Affected

- tolvaptan

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Jynarque.
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	18 years and older
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 tolvaptan and has received less than 30 days of therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOPICAL AGENTS FOR ATOPIC DERMATITIS

Products Affected

- pimecrolimus
- tacrolimus topical

PA Criteria	Criteria Details
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOPICAL RETINOID PRODUCTS

Products Affected

- tretinoin topical

PA Criteria	Criteria Details
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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOPIRAMATE/ZONISAMIDE

Products Affected

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

PA Criteria	Criteria Details
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 1 year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRANSDERMAL FENTANYL

Products Affected

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

PA Criteria	Criteria Details
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, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried 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. Patients with cancer, sickle cell disease, in hospice or who reside in a long term care facility are not required to meet above criteria. 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

- fentanyl citrate buccal lozenge on a handle

PA Criteria	Criteria Details
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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRIENTINE

Products Affected

- trientine oral capsule 250 mg

PA Criteria	Criteria Details
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 1 year
Other Criteria	For Wilson's Disease, approve if the patient meets A and B: A) Diagnosis of Wilson's disease is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, or d): a. Presence of Kayser-Fleischer rings, OR b. Serum ceruloplasmin levels less than 20mg/dL, OR c. Liver biopsy findings consistent with Wilson's disease, OR d. 24-hour urinary copper greater than 40 micrograms/24 hours, AND B) 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, OR 6) the patient has been started on therapy with trientine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

TRIKAFTA

Products Affected

- Trikafta oral granules in packet, sequential
- Trikafta oral tablets, sequential

PA Criteria	Criteria Details
Exclusion Criteria	Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko.
Required Medical Information	Diagnosis, specific CFTR gene mutations, concurrent medications
Age Restrictions	2 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 F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRODELVY

Products Affected

- Trodelvy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-approve if the patient has recurrent or metastatic, human epidermal growth factor receptor (HER2) negative breast cancer and patient meets (a or b): a) patient has hormone receptor (HR) negative disease AND has tried at least two systemic regimens, OR b) patient has HR positive disease, has tried endocrine therapy, has tried a cyclin-dependent kinase(CDK) 4/6 inhibitor and has tried at least two systemic chemotherapy regimens . Urothelial Cancer-approve if the patient has locally advanced or metastatic urothelial cancer AND has tried at least one systemic chemotherapy AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TUKYSA

Products Affected

- Tukysa oral tablet 150 mg, 50 mg

PA Criteria	Criteria Details
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	Breast Cancer-approve if the patient has advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-positive disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TURALIO

Products Affected

- Turalio oral capsule 125 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis)-approve if, according to the prescriber, the tumor is not amenable to improvement with surgery. Histiocytic Neoplasms-approve if the patient has a colony stimulating factor 1 receptor (CSF1R) mutation AND has one of the following conditions (i, ii, or iii): i. Langerhans cell histiocytosis OR ii. Erdheim-Chester disease OR iii. Rosai-Dorfman disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic Neoplasms
Part B Prerequisite	No

TYSABRI

Products Affected

- Tysabri

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of other disease-modifying agents used for MS. Concurrent use with immunosuppressants (eg, 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) in Crohn's disease (CD) patients.
Required Medical Information	Diagnosis
Age Restrictions	Adults (initial and continuation)
Prescriber Restrictions	MS. Prescribed by, or in consultation with, a neurologist or physician who specializes in the treatment of MS (initial and continuation). CD. Prescribed by or in consultation with a gastroenterologist (initial and continuation).
Coverage Duration	MS-Authorization will be for 1 year .CD, initial-6 mo. CD, cont therapy-1 year.
Other Criteria	Adults with a relapsing form of MS-initial. Approve if the patient is new to therapy and has had a trial of generic dimethyl fumarate (prior treatment with Tecfidera, Bafiertam or Vumerity also counts. Also, a patient who has previously tried a glatiramer product (Copaxone, Glatopa, generic) can bypass the requirement of a trial of generic dimethyl fumarate) OR approve if the patient has highly active or aggressive multiple sclerosis by meeting one of the following: a) rapidly advancing deterioration in physical functioning Note: examples include loss of mobility/or lower levels of ambulation, severe changes in strength or coordination, b) disabling relapse with suboptimal response to systemic corticosteroids, c) magnetic resonance imaging (MRI) findings suggest highly active or aggressive multiple sclerosis Note: Examples include new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions, or d) manifestations of multiple sclerosis-related cognitive impairment OR patient has previously received one of the following therapies: Lemtrada, Ocrevus, or Kesimpta.Continuation-approve if the patient has had a response to Tysabri.Adults with CD, initial. Patient has moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein) and patient has tried two of the following agents for CD for at least 2 months

PA Criteria	Criteria Details
	each: adalimumab, certolizumab pegol, infliximab, vedolizumab, ustekinzumab, OR pt has had an inadequate response or was intolerant to these agents. CD, continuation therapy. Patient has had a response to Tysabri, as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

UBRELVY

Products Affected

- Ubrelvy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine, Acute treatment-approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

UPTRAVI

Products Affected

- Uptravi oral

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Confirmation of right heart catheterization, medication history.
Age Restrictions	N/A
Prescriber Restrictions	PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH 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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VALCHLOR

Products Affected

- Valchlor

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Cutaneous lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has chronic/smoldering subtype of adult T-cell leukemia/lymphoma. Langerhans cell histiocytosis-approve if the patient has unifocal Langerhans cell histiocytosis with isolated skin disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adults with T-cell leukemia/lymphoma, Langerhans Cell Histiocytosis
Part B Prerequisite	No

VALTOCO

Products Affected

- Valtoco

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other medications used at the same time
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VANCOMYCIN

Products Affected

- vancomycin oral capsule 125 mg, 250 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 weeks
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VANFLYTA

Products Affected

- Vanflyta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Acute Myeloid Leukemia: approve if the patient has FLT3-ITD mutation-positive disease as detected by an approved test and this medication is being used for induction, consolidation, or maintenance treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VENCLEXTA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Systemic light chain amyloidosis-approve if the patient has t (11, 14) translocation and has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Mantle Cell Lymphoma, waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, multiple myeloma, systemic light chain amyloidosis
Part B Prerequisite	No

VERZENIO

Products Affected

- Verzenio

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Breast cancer, early-approve for 2 years, all other-3 years
Other Criteria	Breast Cancer, Early-Approve if pt meets (A,B,C and D): A)Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets the following:Pt has node-positive disease at high risk of recurrence (Note-High risk includes patients with greater than or equal to 4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: Grade 3 disease, tumor size greater than or equal to 5 cm, or a Ki-67 score of greater than or equal to 20percent) AND D)Pt meets ONE of the following (i or ii): i.Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one of the following (a,b, or c): a)Pt is a postmenopausal woman, OR b)Pt is a pre/perimenopausual woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, OR 2-Pt has had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is a man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets one of the following (a or b): a)Pt is a postmenopausal woman or man OR b)Pt is a pre/perimenopausual woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Patient has had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer,Recurrent or Metastatic in Women-Approve if pt meets (A, B, C and D): A) Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i or ii): i.Pt is a

PA Criteria	Criteria Details
	postmenopausal woman, OR ii.Pt is a pre/perimenopausal woman and meets one of the following (a or b): a)Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt has had surgical bilateral oophorectomy or ovarian irradiation, AND D)Pt meets ONE of the following criteria (i, ii, or iii): i.Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least one prior endocrine therapy, AND c)Pt has tried chemotherapy for metastatic breast cancer.Breast Cancer,Recurrent or Metastatic in Men-Approve if pt meets the following criteria (A,B and C): A)Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)Pt is receiving a GnRH analog, AND b)Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.Pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least one prior endocrine therapy, AND c)Pt has tried chemotherapy for metastatic breast cancer.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	treatment of advanced or metastatic breast cancer in combination with an aromatase inhibitor in pre-menopausal women
Part B Prerequisite	No

VIMIZIM

Products Affected

- Vimizim

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine-6-sulfatase activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating N-acetylgalactosamine-6-sulfatase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VISTOGARD

Products Affected

- Vistogard

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	Capecitabine or fluorouracil overdose-approve. Capecitabine or fluorouracil toxicity, severe or life threatening-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VITRAKVI

Products Affected

- Vitrakvi oral capsule 100 mg, 25 mg
- Vitrakvi oral solution

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, NTRK gene fusion status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Solid tumors - approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VIZIMPRO

Products Affected

- Vizimpro

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, EGFR status, exon deletions or substitutions
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	NSCLC-approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VONJO

Products Affected

- Vonjo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Myelofibrosis (MF), including primary MF, post-polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has intermediate risk or high risk disease and the patient has a platelet count of less than 50 X 10 9/L (less than 50,000/mcL)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VORICONAZOLE (ORAL)

Products Affected

- voriconazole

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Aspergillus-Prophy, systemic w/risk neutropenia-Prophy, systemic w/HIV-Prophy/Tx-6 mo, others-3 mo
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Aspergillus Infections - prophylaxis, oropharyngeal candidiasis (fluconazole-refractory) - treatment, candidia endophthalmitis - treatment, blastomycosis - treatment, fungal infections (systemic) in patients at risk of neutropenia - prophylaxis, fungal infections (systemic) in patients with human immunodeficiency virus (HIV) - prophylaxis or treatment.
Part B Prerequisite	No

VOSEVI

Products Affected

- Vosevi

PA Criteria	Criteria Details
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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No

VOTRIENT

Products Affected

- Votrient

PA Criteria	Criteria Details
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 solitary fibrous tumor/hemangiopericytoma or alveolar soft part 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 Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or stage IV disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. 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).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma.

PA Criteria	Criteria Details
Part B Prerequisite	No

VUMERITY

Products Affected

- Vumerity

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Cont tx-approve if the patient has been established on Vumerity.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

WELIREG

Products Affected

- Welireg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Van Hippel-Lindau Disease-approve if the patient meets the following (A, B, and C): A) Patient has a von Hippel-Lindau (VHL) germline alteration as detected by genetic testing, B) Does not require immediate surgery and C) Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv): i. Central nervous system hemangioblastomas, OR ii. Pancreatic neuroendocrine tumors, OR iii. Renal cell carcinoma, OR iv. Retinal hemangioblastoma.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XALKORI

Products Affected

- Xalkori

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Dignosis
Age Restrictions	Anaplastic large cell lymphoma-patients greater than or equal to 1 year of age. All other diagnoses (except soft tissue sarcoma)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test or ROS1 rearrangement positive disease, as detected by an approved test. Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test or ROS1 rearrangement positive disease, as detected by an approved test. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND has received at least one prior systemic treatment. Histiocytic neoplasm-approve if the patient has ALK rearrangement/fusion-positive disease and meets one of the following criteria (i, ii, or iii): (i. Patient has Langerhans cell histiocytosis, OR ii. Patient has Erdheim-Chester disease OR iii. Patient has Rosai-Dorfman disease. NSCLC with MET mutation-approve if the patient has high level MET amplification or MET exon 14 skipping mutation. Soft Tissue Sarcoma - Inflammatory Myofibroblastic Tumor with Anaplastic Lymphoma Kinase (ALK) Translocation-approve. Melanoma, cutaneous-approve if the patient has ALK fusion disease or ROS1 fusion disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous.

PA Criteria	Criteria Details
Part B Prerequisite	No

XDEMVY

Products Affected

- Xdemvy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XELJANZ

Products Affected

- Xeljanz oral solution
- Xeljanz oral tablet
- Xeljanz XR

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a Targeted Synthetic DMARD 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	AS/PsA/RA/UC-18 years and older (initial therapy)
Prescriber Restrictions	RA, JIA/JRA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist.
Coverage Duration	1 year
Other Criteria	RA initial-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. PsA initial, approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial and the requested medication will be used in combination with methotrexate or another conventional synthetic disease modifying antirheumatic drug (DMARD), unless contraindicated. UC-Approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis or was unable to tolerate a 3-month trial. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis]-initial-approve Xeljanz immediate release tablets or solution if the patient meets the following: patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AS-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least

PA Criteria	Criteria Details
	one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XERMELO

Products Affected

- Xermelo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
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]) 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XIAFLEX

Products Affected

- Xiaflex

PA Criteria	Criteria Details
Exclusion Criteria	Retreatment (i.e., treatment beyond three injections per affected cord for those with Dupuytren's Contracture or beyond eight injections for Peyronie's Disease).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Dupuytren's Contracture-administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture. Peyronie's Disease -administered by a healthcare provider experienced in the treatment of male urological diseases.
Coverage Duration	Dupuytren's Contracture-3 months, Peyronie's Disease-6 months
Other Criteria	Dupuytren's Contracture-at baseline (prior to initial injection of Xiaflex), the patient had contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint of at least 20 degrees AND the patient will not be treated with more than a total of three injections (maximum) per affected cord. Peyronie's Disease-the patient meets ONE of the following (i or ii): i. at baseline (prior to use of Xiaflex), the patient has a penile curvature deformity of at least 30 degrees OR in a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees AND the patient has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XOLAIR

Products Affected

- Xolair subcutaneous recon soln
- Xolair subcutaneous syringe 150 mg/mL, 75 mg/0.5 mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with an Interleukin (IL) Antagonist Monoclonal Antibody
Required Medical Information	Moderate to severe persistent asthma, baseline IgE level of at least 30 IU/mL. For asthma, patient has a baseline 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). CIU - must have urticaria for more than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine).
Age Restrictions	Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years and older.
Prescriber Restrictions	Moderate to severe persistent asthma 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. Polyps-prescribed by or in consult with an allergist, immunologist, or otolaryngologist.
Coverage Duration	asthma/CIU-Initial tx 4 months, Polyps-initial-6 months, continued tx 12 months
Other Criteria	Moderate to severe persistent asthma approve if pt meets criteria 1 and 2: 1) pt has received at least 3 months of combination therapy with an inhaled corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2) patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring

PA Criteria	Criteria Details
	hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80 percent predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For CIU cont tx - must have responded to therapy as determined by the prescribing physician. Nasal Polyps Initial-Approve if the patient has a baseline IgE level greater than or equal to 30 IU/ml, patient is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell and patient is currently receiving therapy with an intranasal corticosteroid. Nasal polyps continuation-approve if the patient continues to receive therapy with an intranasal corticosteroid and has responded to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XOSPATA

Products Affected

- Xospata

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, FLT3-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	AML - approve if the patient has relapsed or refractory disease AND the disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Lymphoid, Myeloid Neoplasms
Part B Prerequisite	No

XPOVIO

Products Affected

- Xpovio oral tablet 100 mg/week (50 mg x 2), 40 mg/week (40 mg x 1), 40mg twice week (40 mg x 2), 60 mg/week (60 mg x 1), 60mg twice week (120 mg/week), 80 mg/week (40 mg x 2), 80mg twice week (160 mg/week)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Multiple Myeloma-Approve if the patient meets the following (A and B): A) The medication will be taken in combination with dexamethasone AND B) Patient meets one of the following (i, ii, or iii): i. Patient has tried at least four prior regimens for multiple myeloma OR ii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib OR iii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with Darzalex (daratumumb infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples of regimens for multiple myeloma include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Kyprolis (carfilzomib infusion)/Revlimid/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma-approve if the patient has been treated with at least two prior systemic therapies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Treatment of multiple myeloma in combination with daratumumb or pomalidomide
Part B Prerequisite	No

XTANDI

Products Affected

- Xtandi oral capsule
- Xtandi oral tablet 40 mg, 80 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Xtandi is being used.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	Prostate cancer-castration-resistant [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) agonist or the medication is concurrently used with Firmagon or if the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XYREM

Products Affected

- sodium oxybate
- Xyrem

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Xywav, Wakix or Sunosi
Required Medical Information	Medication history
Age Restrictions	7 years and older
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, 18 years and older - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). For EDS in patients with narcolepsy, less than 18 years old-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextramphetamine) or modafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

YONSA

Products Affected

- Yonsa

PA Criteria	Criteria Details
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 or dexamethasone and the patient meets ONE of the following criteria (i or ii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZARXIO

Products Affected

- Zarxio

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
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. Radiation-expertise in acute radiation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6mo.HIV/AIDS-4mo.MDS-3mo.PBPC,Drug induce A/N,AA,ALL,BMT- 3mo. Radi-1mo. Other-12mo.
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 percent 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 percent 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), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgramstim products, pegfilgrastim products) 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

PA Criteria	Criteria Details
	[absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	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). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome).
Part B Prerequisite	No

ZEJULA

Products Affected

- Zejula oral capsule
- Zejula oral tablet 100 mg, 200 mg, 300 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after platinum-based chemotherapy regimen. Uterine leiomyosarcoma-approve if the patient has BRCA2 mutation and has tried one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma
Part B Prerequisite	No

ZELBORAF

Products Affected

- Zelboraf

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	BRAFV600 mutation status required.
Age Restrictions	All diagnoses (except CNS cancer)-18 years and older
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 unresectable, advanced or metastatic melanoma. HCL - must have tried at least one other systemic therapy for hairy cell leukemia OR is unable to tolerate purine analogs and Zelboraf will be used in combination with Gazyva (obinutuzumab intravenous infusion) as initial therapy. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. Erdheim-Chester disease, in patients with the BRAF V600 mutation-approve. Central Nervous System Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i) adjuvant treatment of pilocytic astrocytoma OR pleomorphic xanthoastrocytoma OR ganglioglioma, OR ii) recurrent disease for one of the following conditions: low-grade glioma OR anaplastic glioma OR glioblastoma, OR iii) melanoma with brain metastases AND the medication with be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following: multisystem disease OR pulmonary disease OR central nervous system lesions AND the patient has BRAF V600-mutation positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e.,

PA Criteria	Criteria Details
	papillary, follicular, or Hurthle cell) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm
Part B Prerequisite	No

ZEPOSIA

Products Affected

- Zeposia
- Zeposia Starter Kit (28-day)
- Zeposia Starter Pack (7-day)

PA Criteria	Criteria Details
Exclusion Criteria	MS-Concurrent use with other disease-modifying agents used for multiple sclerosis.UC- Concurrent Use with a Biologic or with a Targeted Synthetic Disease-modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis
Required Medical Information	Diagnosis
Age Restrictions	UC-18 years and older
Prescriber Restrictions	MS-Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. UC-Prescribed by or in consultation with a gastroenterologist
Coverage Duration	1 year
Other Criteria	MS-approve. Ulcerative Colitis, initial-approve if the patient has tried Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz or Amjevita (NDCs starting with 55513-). Note-a trial of Simponi SC, Amjevita (NDCs starting with 72511), any other non-preferred adalimumab or infliximab would also count). Cont tx-approve if the patient has been established on Zeposia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZEPZELCA

Products Affected

- Zepzelca

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Small cell lung cancer-approve if the patient has metastatic disease and has previously received platinum-based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZIEXTENZO

Products Affected

- Ziextenzo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-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 percent 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 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No

ZOLINZA

Products Affected

- Zolinza

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZTALMY

Products Affected

- Ztalmy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder-approve if the patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZYDELIG

Products Affected

- Zydelig

PA Criteria	Criteria Details
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
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	small lymphocytic lymphoma
Part B Prerequisite	No

ZYKADIA

Products Affected

- Zykadia

PA Criteria	Criteria Details
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	Erdheim-Chester Disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Soft Tissue Sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement. Erdheim-Chester disease.
Part B Prerequisite	No

ZYNLONTA

Products Affected

- Zynlonta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse Large B-Cell Lymphoma- approve if the patient has tried at least two systemic regimens.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZYNYZ

Products Affected

- Zynyz

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. Merkel Cell Carcinoma-approve if the patient has not received prior systemic therapy for Merkel cell carcinoma and if the patient has metastatic disease or has recurrent locally advanced disease or recurrent regional disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZYTIGA

Products Affected

- abiraterone oral tablet 250 mg, 500 mg

PA Criteria	Criteria Details
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)-Approve if abiraterone is being used in combination with prednisone or dexamethasone and the medication is concurrently used with a gonadotropin-releasing hormone (GnRH) agonist, or the medication is concurrently used with Firmagon or the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration-sensitive (mCSPC)-approve if the medication is used in combination with prednisone and the medication is concurrently used with a GnRH agonist or concurrently used with Firmagon or the patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the patient meets all of the following criteria (A, B, and C): A)abiraterone 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, ii or iii): i.abiraterone with prednisone is used in combination with GnRH agonist OR ii. Patient has had a bilateral orchiectomy OR iii. the medication is used in combination with Firmagon. Prostate cancer-very-high-risk-group-approve if according to the prescriber the patient is in the very-high-risk group, the medication will be used in combination with external beam radiation therapy and the patient meets one of the following criteria (i, ii or iii): i. abiraterone is used in combination with GnRH agonist OR ii. Patient has had a bilateral orchiectomy OR iii. the medication is used in combination with Firmagon. Prostate cancer-radical

PA Criteria	Criteria Details
	prostatectomy-approve if the medication is used in combination with prednisone, the patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy, patient has pelvic recurrence, the medication will be used concurrently with GnRH agonist, Firmagon or the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Prostate Cancer-Regional Risk Group, Prostate cancer-very-high-risk group, Prostate cancer-radical prostatectomy
Part B Prerequisite	No

PART B VERSUS PART D

Products Affected

- Abelcet
- Abraxane
- acetylcysteine
- Actimmune
- acyclovir sodium intravenous solution
- Adcetris
- albuterol sulfate inhalation solution for nebulization
- Alimta
- Aliqopa
- amiodarone intravenous
- amphotericin B
- aprepitant
- arformoterol
- arsenic trioxide
- azacitidine
- azathioprine oral tablet 50 mg
- azathioprine sodium
- Bavencio
- Beleodaq
- bendamustine intravenous recon soln
- Bendeka
- Besponsa
- bleomycin
- Blincyto intravenous kit
- bortezomib injection recon soln 1 mg, 2.5 mg
- bortezomib injection recon soln 3.5 mg
- budesonide inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
- busulfan
- carboplatin intravenous solution
- carmustine intravenous recon soln 100 mg
- cidofovir
- cisplatin intravenous solution
- cladribine
- Clinimix 5%/D15W Sulfite Free
- Clinimix 4.25%/D10W Sulf Free
- Clinimix 4.25%/D5W Sulfit Free
- Clinimix 5%-D20W(sulfite-free)
- Clinimix 6%-D5W (sulfite-free)
- Clinimix 8%-D10W(sulfite-free)
- Clinimix 8%-D14W(sulfite-free)
- clofarabine
- Cosmegen
- cromolyn inhalation
- cyclophosphamide intravenous recon soln
- cyclophosphamide oral capsule
- cyclophosphamide oral tablet
- cyclosporine intravenous
- cyclosporine modified
- cyclosporine oral capsule
- Cyramza
- cytarabine
- cytarabine (PF)
- dacarbazine
- dactinomycin
- Darzalex
- daunorubicin intravenous solution
- decitabine
- deferoxamine
- dexrazoxane HCl
- dobutamine
- dobutamine in D5W intravenous parenteral solution 1,000 mg/250 mL (4,000 mcg/mL), 250 mg/250 mL (1 mg/mL), 500 mg/250 mL (2,000 mcg/mL)
- docetaxel
- dopamine in 5 % dextrose
- dopamine intravenous solution 200 mg/5 mL (40 mg/mL), 400 mg/10 mL (40 mg/mL)
- doxorubicin
- doxorubicin, peg-liposomal
- dronabinol
- Emend oral suspension for reconstitution
- Empliciti
- Engerix-B (PF)
- Engerix-B Pediatric (PF)
- Envarsus XR
- epirubicin intravenous solution 200 mg/100 mL
- Erbitux
- Erwinase
- Etopophos

- etoposide intravenous
- everolimus (immunosuppressive)
- Firmagon kit w diluent syringe
- floxuridine
- fludarabine
- fluorouracil intravenous
- Folotyn
- formoterol fumarate
- fulvestrant
- ganciclovir sodium
- Gazyva
- gemcitabine intravenous recon soln
- gemcitabine intravenous solution 1 gram/26.3 mL (38 mg/mL), 2 gram/52.6 mL (38 mg/mL), 200 mg/5.26 mL (38 mg/mL)
- gemcitabine intravenous solution 100 mg/mL
- Gengraf
- granisetron HCl oral
- Halaven
- Heplisav-B (PF)
- Hizentra
- HyQvia
- idarubicin
- ifosfamide
- Imfinzi
- Intralipid intravenous emulsion 20 %
- ipratropium bromide inhalation
- ipratropium-albuterol
- irinotecan
- Istodax
- Ixempra
- Jevtana
- Jynneos (PF)(Stockpile)
- Khapzory
- Kyprolis
- levalbuterol HCl
- levoleucovorin calcium
- Lioresal
- melphalan
- melphalan HCl
- mesna
- methotrexate sodium
- methotrexate sodium (PF)
- methylprednisolone oral tablet
- milrinone
- milrinone in 5 % dextrose
- mitomycin intravenous
- mitoxantrone
- Mozobil
- mycophenolate mofetil
- mycophenolate mofetil (HCl)
- mycophenolate sodium
- Mylotarg
- nelarabine
- nitroglycerin in 5 % dextrose intravenous solution 100 mg/250 mL (400 mcg/mL), 25 mg/250 mL (100 mcg/mL), 50 mg/250 mL (200 mcg/mL)
- nitroglycerin intravenous
- Nulojix
- Oncaspar
- ondansetron
- ondansetron HCl oral solution
- ondansetron HCl oral tablet 4 mg, 8 mg
- Onivyde
- oxaliplatin
- paclitaxel
- Paraplatin
- pemetrexed disodium intravenous recon soln
- pentamidine inhalation
- Perjeta
- Plenamine
- plerixafor
- Portrazza
- Prehevbrio (PF)
- Premasol 10 %
- Prograf intravenous
- Prograf oral granules in packet
- Pulmozyme
- Recombivax HB (PF)
- romidepsin intravenous recon soln
- Sandimmune oral solution
- Simulect
- sirolimus
- sodium nitroprusside
- Synribo
- tacrolimus oral
- Tecentriq
- Temodar intravenous

- temsirolimus
- thiotepa
- Tice BCG
- topotecan
- Travasol 10 %
- Trazimera
- Treanda
- Trelstar intramuscular suspension for reconstitution
- TrophAmine 10 %
- Unituxin
- valrubicin
- Varubi
- Vectibix
- Veletri
- vinblastine
- vincristine
- vinorelbine
- Vyxeos
- Xatmep
- Xgeva
- Yervoy
- Yondelis
- Zaltrap
- Zanosar
- Zirabev
- zoledronic acid intravenous solution
- zoledronic acid-mannitol-water intravenous piggyback 4 mg/100 mL

Details

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

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