2024 Prior Authorization (PA) Criteria

Certain drugs require prior authorization from EmblemHealth Medicare PDP Medicare Plans. This means that your doctor must contact us to get approval before prescribing the drug to you. If your doctor does not get prior approval, the drug may not be covered.

This list also includes drugs that may be covered under Medicare Part B or Part D depending on how the drugs are used or administered. If your drug is on this list, your doctor should call us and to provide information describing the use and administration of the drug so we can advise on whether the drug will be covered.

To see if your drug is on the list refer to the index located at the end of this document for the medication you are looking for.

Updated 04/2024 Y0026_204255_C

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. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).
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	Approve through 12/31/24.
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, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], 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, or a non-preferred adalimumab product will also count. A trial of multiple adalimumab products counts as ONE 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, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm]. (Note: if the patient does not meet this requirement, a previous trial with the drug infliximab or

PA Criteria	Criteria Details
	a non-preferred adalimumab product will be counted towards meeting the try TWO requirement. A trial of multiple adalimumab products counts as ONE product.), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx, RA/PJIA - approve if the pt had a response as determined by the prescriber.
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). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
Coverage Duration	Approve through 12/31/24.
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, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz, adalimumab-adbm], 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, or another non-preferred adalimumab product will also count. Trials of multiple adalimumab products count as ONE preferred. 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, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz, adalimumab-adbm]. (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. Trials of multiple adalimumab products counts as

PA Criteria	Criteria Details
	ONE Preferred Product.), OR B) patient has heart failure or a previously 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

ACTHAR

Products Affected

- Acthar

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber or consulting physician specialty, previous medications tried and response
Age Restrictions	Infantile spasms- less than 2yo. Acute MS exac-adult
Prescriber Restrictions	Infant spasms, prescr physician who consulted w/specializes in neurology. MS exacer, prescr/consult w/neuro/phys specializes MS.RA, JIA/JRA, AS, PsA, SLE, Systemic Dermatomyositis, prescr/consult w/rheum.Severe Erythema Multiforme, prescr/consult w/derm.Serum Sickness,prescr/consult w/allergist.Severe acute/chronic allergic/inflamm processes of eye and its adnexa, prescr/consult w/ ophthalmologist.Symptomatic Sarcoidosis, prescr/consult w/pulm/cardio.Nephrotic Syndrome, prescr/consult w/nephro.
Coverage Duration	All diagnoses-1 month
Other Criteria	For acute MS exacerbation, approve if Acthar is NOT being used as pulse therapy on a monthly basis. For all other FDA approved diagnoses (other than Infantile spasms or MS exacerbation), approve if the patient has tried a systemic corticosteroid for the current condition and patient has experienced a severe adverse effect or treatment failure with the corticosteroid (e.g., a psychotic reaction). In addition, for all covered diagnoses, except infantile spasms, patients must have a trial of Cortrophin prior to approval of Acthar.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

ACYCLOVIR (TOPICAL)

Products Affected

- acyclovir topical cream
- acyclovir topical ointment
- Zovirax topical cream
- Zovirax topical ointment

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Medication history (as described in Other Criteria field)
Age Restrictions	Acyclovir 5 percent cream, 12 yrs or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	If the request is for brand name Zovirax 5 percent ointment, the patient is required to have tried generic acyclovir 5 percent ointment AND cannot use the generic product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADAKVEO

Products Affected

- Adakveo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	16 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (initial and continuation)
Coverage Duration	1 year
Other Criteria	Sickle Cell Disease Initial-approve if the patient has had at least one sickle cell-related crisis in the previous 12-month period, AND patient meets one of the following criteria (a, b, or c): a. Patient is currently receiving a hydroxyurea product OR b. patient has tried a hydroxyurea product and has experienced inadequate efficacy or significant intolerance OR c. patient is not a candidate for hydroxyurea therapy. Cont-approve if the patient is receiving clinical benefit from Adakveo therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADALIMUMAB OTHER

Products Affected

- Abrilada(CF) Pen
- Abrilada(CF) subcutaneous syringe kit 20 mg/0.4 mL, 40 mg/0.8 mL
- adalimumab-aacf
- adalimumab-adaz
- adalimumab-adbm subcutaneous pen injector kit
- adalimumab-adbm subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL
- adalimumab-adbm(CF) pen Crohns
- adalimumab-adbm(CF) pen PS-UV
- adalimumab-fkjp subcutaneous pen injector kit
- adalimumab-fkjp subcutaneous syringe kit 20 mg/0.4 mL, 40 mg/0.8 mL
- 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
- Hadlima
- Hadlima PushTouch
- Hadlima(CF)
- Hadlima(CF) PushTouch
- Hulio(CF) Pen
- Hulio(CF) subcutaneous syringe kit 20 mg/0.4 mL, 40 mg/0.8 mL
- Hyrimoz
- Hyrimoz CF (Preferred NDCs starting with 61314) subcutaneous pen injector 40 mg/0.4 mL, 80 mg/0.8 mL
- Hyrimoz CF (Preferred NDCs starting with 61314) subcutaneous syringe 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL
- Hyrimoz Pen
- 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
- Idacio(CF)
- Idacio(CF) Pen
- Idacio(CF) Pen Crohn-UC Startr
- Idacio(CF) Pen Psoriasis Start
- Yuflyma(CF) AI Crohn's-UC-HS
- Yuflyma(CF) Autoinjector subcutaneous auto-injector, kit 40 mg/0.4 mL, 80 mg/0.8 mL
- Yuflyma(CF) subcutaneous syringe kit 40 mg/0.4 mL
- Yusimry(CF) Pen

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

PA Criteria	Criteria Details
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	Approve through 12/31/24.
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 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.,systemic antibiotics, isotretinoin). cont tx - must respond to tx as determined by prescriber. In addition to above criteria, patients requesting Hadlima, Yusimry, Hulio, Hyrimoz (NDCs starting with 83457-),

PA Criteria	Criteria Details
	Yuflyma, Idacio, Abrilada or Adalimumab-fkjp must have a trial of TWO of the following preferred products: Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adbm, Adalimumab-adaz prior to approval.
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 (i.e., Dupixent, Cinqair, Fasenra, Nucala, Tazespire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical].
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-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	Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.
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

ADZYNMA

Products Affected

- Adzynma

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	Congenital thrombotic thrombocytopenic purpura-Approve if the patient meets the following (A, B and C): A) At baseline (prior to therapy) ADAMTS13 activity is less than 10 percent (less than 10 IU/dL), Note: Baseline refers to before any treatment was received, such as Adzynma or plasma-based therapies. AND B) Patient does not have anti-ADAMTS13 autoantibodies as determined by a diagnostic test, AND C) Patient has a pathogenic variant or a mutation in the ADAMTS13 gene. Note: Pathogenic variants or gene mutations are usually homozygous or compound heterozygous.
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

AJOVY

Products Affected

- Ajovy Autoinjector
- Ajovy Syringe

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Aimovig, 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 Aimovig or Emgality.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AKEEGA

Products Affected

- Akeega

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	Prostate cancer- Approve if the patient meets the following (A, B, C, and D): A)Patient has metastatic castration-resistant prostate cancer, AND B)Patient has a BReast CAncer (BRCA) mutation, AND C)The medication is used in combination with prednisone, AND D)Patient meets one of the following (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog, Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), and Orgovyx (relugolix tablets).OR ii. Patient has had a bilateral orchiectomy.
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	1 year
Other Criteria	Non-small cell lung cancer-approve if the patient has advanced or metastatic disease and anaplastic lymphoma kinase (ALK)-positive disease as detected by an approved test. Anaplastic large cell lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease and (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor- pt has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) pt has advanced, recurrent or metastatic disease, or (ii) tumor is inoperable. Large B-Cell Lymphoma- pt has ALK-positive disease AND pt has relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma

PA Criteria	Criteria Details
Part B Prerequisite	No

ALOSETRON

Products Affected

- alosetron
- Lotronex

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

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- Aralast NP
- Glassia
- Prolastin-C
- Zemaira

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	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
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 ALK positive disease and has advanced, recurrent or metastatic disease or the tumor is inoperable. NSCLC, must be ALK-positive, as detected by an approved test, have advanced or metastatic disease and patients new to therapy must have a trial of Alecensa prior to approval of Alunbrig.
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 (Preferred NDCs starting with 55513) subcutaneous auto-injector 40 mg/0.4 mL, 40 mg/0.8 mL, 80 mg/0.8 mL
- Amjevita (Preferred NDCs starting with 55513) subcutaneous syringe 10 mg/0.2 mL, 20 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.4 mL, 40 mg/0.8 mL

PA Criteria	Criteria Details
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	Approve through 12/31/24.
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

PA Criteria	Criteria Details
	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 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. In addition to above criteria, patients must have a trial of Humira, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adbm or adalimumab-adaz prior to approval of Amjevita.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AMONDYS

Products Affected

- Amondys-45

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	DMD- patient has a confirmed mutation of the DMD gene that is amenable to exon 45 skipping
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AMVUTTRA

Products Affected

- Amvuttra

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Onpattro (patisiran intravenous injection), Tegsedi (inotersen subcutaneous injection), or a Tafamidis Product
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis
Coverage Duration	1 year
Other Criteria	Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR)-approve if the patient meets (A, B and C)-A) Patient has a transthyretin mutation as confirmed by genetic testing, AND B) Patient has symptomatic polyneuropathy, AND Note: Examples of symptomatic polyneuropathy include reduced motor strength/coordination, and impaired sensation (e.g., pain, temperature, vibration, touch). Examples of assessments for symptomatic disease include history and clinical exam, electromyography, or nerve conduction velocity testing. C) Patient does not have a history of liver transplantation.
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
- Avycaz
- Azactam
- azithromycin intravenous
- aztreonam
- Baxdela intravenous
- Bicillin C-R
- Bicillin L-A
- cefotetan injection
- cefoxitin
- cefoxitin in dextrose, iso-osm
- ceftazidime
- cefuroxime sodium injection recon soln 750 mg
- cefuroxime sodium intravenous
- ciprofloxacin in 5 % dextrose
- Cleocin injection
- clindamycin in 0.9 % sod chlor
- clindamycin in 5 % dextrose
- clindamycin phosphate injection
- clindamycin phosphate intravenous
- colistin (colistimethate Na)
- Coly-Mycin M Parenteral
- Dalvance
- Doxy-100
- doxycycline hyclate intravenous
- ertapenem
- Erythrocin intravenous recon soln 500 mg
- erythromycin lactobionate
- Fetroja
- gentamicin in NaCl (iso-osm) intravenous piggyback 100 mg/100 mL, 60 mg/50 mL, 80 mg/100 mL, 80 mg/50 mL
- gentamicin in NaCl (iso-osm) intravenous piggyback 100 mg/50 mL, 120 mg/100 mL
- gentamicin injection solution 40 mg/mL
- gentamicin sulfate (ped) (PF)
- imipenem-cilastatin
- Invanz injection
- Kimyrsa
- levofloxacin in D5W
- levofloxacin intravenous
- Lincocin
- lincomycin
- linezolid in dextrose 5%
- linezolid-0.9% sodium chloride
- meropenem intravenous recon soln 1 gram, 500 mg
- meropenem-0.9% sodium chloride intravenous piggyback 1 gram/50 mL, 500 mg/50 mL
- Metro I.V.
- metronidazole in NaCl (iso-os)
- Minocin intravenous
- moxifloxacin-sod.ace,sul-water
- moxifloxacin-sod.chloride(iso)
- nafcillin in dextrose iso-osm
- nafcillin injection
- nafcillin intravenous recon soln 2 gram
- Nuzyra intravenous
- Orbactiv
- oxacillin in dextrose(iso-osm)
- oxacillin injection
- penicillin G pot in dextrose
- penicillin G potassium
- penicillin G sodium
- Pfizerpen-G
- polymyxin B sulfate
- Primaxin IV intravenous recon soln 500 mg

- Sivextro intravenous
- streptomycin
- sulfamethoxazole-trimethoprim intravenous
- Tazicef
- Teflaro
- tigecycline
- tobramycin sulfate injection recon soln
- tobramycin sulfate injection solution
- Tygacil
- Unasyn injection
- Vabomere
- vancomycin in 0.9 % sodium chl intravenous piggyback 1 gram/200 mL, 500 mg/100 mL, 750 mg/150 mL
- vancomycin in dextrose 5 % 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
- vancomycin intravenous recon soln 1.25 gram, 1.5 gram
- vancomycin-diluent combo no.1 intravenous piggyback 1 gram/200 mL, 1.25 gram/250 mL, 1.5 gram/300 mL, 1.75 gram/350 mL, 2 gram/400 mL, 500 mg/100 mL, 750 mg/150 mL
- Vibativ intravenous recon soln 750 mg
- Xerava
- Zemdri
- Zerbaxa
- Zithromax intravenous
- Zyvox intravenous

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

PA Criteria	Criteria Details
Part B Prerequisite	No

ANTIFUNGALS (IV)

Products Affected

- Cresemba
- fluconazole in NaCl (iso-osm)
- Noxafil intravenous
- posaconazole intravenous
- Vfend IV
- 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)-approve if the patient meets the following criteria: 1. patient is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, 2. Patient is currently receiving carbidopa/levodopa, 3. 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

ARANESP

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Anemia w/CRF not on dialysis.A hemoglobin (Hb) of less than 10.0 g/dL for adults and less than or equal to 11 g/dL for children required for start,Hb has to be less than or equal 11.5 g/dL adults or less than or equal to 12 g/dL in children if previously receiving epoetin alfa (EA), Mircera or Aranesp. Anemia in a patient with cancer due to cancer chemotherapy, patients must be currently receiving myelosuppressive chemotherapy which is considered non-curative treatment, Hb is 10.0 g/dL or less to start or less than or equal to 12.0 g/dL if previously on EA or Aranesp. MDS, approve tx if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. If the pt has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL.
Age Restrictions	MDS anemia = 18 years of age and older.
Prescriber Restrictions	MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.
Coverage Duration	Anemia w/myelosupp=6 mos, Anemia CKD-1 year, MDS-1 year, Other=6 mos.
Other Criteria	For all covered uses, the patient is required to try Procrit or Retacrit first line. For anemia associated with CRF in patients 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)

PA Criteria	Criteria Details
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 (as described in Other Criteria field)
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	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 according to the laboratory report 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.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Cystic fibrosis pseudomonas aeruginosa infection
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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AUGTYRO

Products Affected

- Augtyro

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-approve if the patient has locally advanced or metastatic disease, patient has ROS1-positive non-small cell lung cancer and the mutation was detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AURYXIA

Products Affected

- Auryxia

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

AUSTEDO

Products Affected

- Austedo oral tablet 12 mg, 6 mg, 9 mg
- Austedo XR oral tablet extended release 24 hr 12 mg, 24 mg, 6 mg
- Austedo XR Titration Kt(Wk1-4)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Chorea-prescribed by or in consult with a neuro. TD-Prescribed by or in consultation with a neurologist or a psychiatrist
Coverage Duration	1 year
Other Criteria	Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing and if the patient has tried tetrabenazine. Tardive dyskinesia-approve.
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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AVSOLA

Products Affected

- Avsola

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medication, medications previously tried
Age Restrictions	CD/UC - Pts aged 6 years or more (initial therapy). Ulcerative Colitis. PP-18 years and older (initial therapy)
Prescriber Restrictions	All dx initial therapy only-Presc/consult with: RA/AS/Still's disease/JIA/JRA-rheum, Plaque Psoriasis/Pyoderma gangrenosum/Hidradenitis suppurativa-derm, Psoriatic Arthritis-rheum or derm, Crohn's Disease/UC-gastroenterologist, Uveitis ophthalmologist, GVHD-a physician affiliated with a transplant center, oncologist, or hematologist, Behcet's Disease- rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist, 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	Initial therapy-for all covered diagnoses-approve if the patient has tried Remicade. 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, Still's disease, Uveitis, Pyoderma gangrenosum, Hidradenitis suppurativa, Graft-versus-host disease, Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis
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	1 year
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

BAFIERTAM

Products Affected

- Bafiertam

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Diagnosis
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	1 year
Other Criteria	Initial treatment - approve if the patient has tried TWO of the following: generic dimethyl fumarate, Vumerity, Gilenya or Aubagio. Note: Prior use of brand Tecfidera with inadequate efficacy or significant intolerance (according to the prescriber) also counts. Cont tx - approve if the patient has been established on Bafiertam.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	1 year
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 if the patient has a diagnosis of lupus nephritis confirmed on biopsy (For example, World Health Organization class III, IV, or V lupus nephritis), AND the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid). Cont-approve if the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid) AND 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.

PA Criteria	Criteria Details
	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
Part B Prerequisite	No

BEOVU

Products Affected

- Beovu intravitreal syringe

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

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
- Extavia

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 Extavia, approve if the patient is new to therapy and has tried two of the following: interferon beta-1a intramuscular (Avonex), pegylated interferon beta-1a (Plegridy), interferon beta-1b (Betaseron), or glatiramer acetate. Cont tx-approve if the patient has been established on Extavia. For patients requesting Betaseron-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BEVACIZUMAB

Products Affected

- Alymsys
- Avastin
- Mvasi
- Vegzelma

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, Vegzelma 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.
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, anaplastic gliomas, intracranial and spinal ependymoma (excluding subependymoma), meningiomas, astrocytoma, oligodendroglioma, pediatric central nervous system tumors, ampullary adenocarcinoma
Part B Prerequisite	No

BEXAROTENE (ORAL)

Products Affected

- bexarotene
- Targretin

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried (as described in Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	If brand Targretin is requested, the patient has tried and cannot take generic bexarotene capsules due to a formulation difference in the inactive ingredient(s) between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BEXAROTENE (TOPICAL)

Products Affected

- bexarotene
- Targretin

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	1 year
Other Criteria	Adult T-Cell Leukemia/Lymphoma- approve if the patient has chronic/smoldering subtype and this medication is used as first-line therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adult T-Cell Leukemia/Lymphoma
Part B Prerequisite	No

BIMZELX

Products Affected

- Bimzelx
- Bimzelx Autoinjector

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	1 year
Other Criteria	Plaque psoriasis, initial therapy-approve if the patient has tried TWO of the following: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, adalimumab adbm, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz], Skyrizi SC, Stelara SC, Otezla or Taltz. A trial of Humira, Cyltezo, adalimumab adbm, Hyrimoz, adalimumab-adaz counts as ONE Preferred Product. Plaque psoriasis, continuation-approve if the patient has had a response.
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

PA Criteria	Criteria Details
	zoledronic acid) OR the patient has had an osteoporotic fracture or a fragility fracture.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BOSENTAN/AMBRISENTAN

Products Affected

- ambrisentan
- bosentan
- Letairis
- Tracleer

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. For all covered diagnoses, if the request is for brand name Tracleer-the patient is required to have tried generic bosentan tablets AND cannot use the generic product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction. For all covered diagnoses, if the request is for brand name Letairis-the patient is required to have tried generic ambrisentan tablets AND cannot use the generic product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the

PA Criteria	Criteria Details
	Brand and the generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction.
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 capsule 100 mg, 50 mg
- 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	CML- 1 year and older. ALL, myeloid/lymphoid neoplasms w eosinophilia-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For Ph-positive CML, patients new to therapy must have tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel. For Ph-positive ALL, patients new to therapy must have tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel.
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, benign essential blepharospasm, seventh (VII) nerve disorders or Strabismus-approve, Cervial Dystonia (spasmodic torticollis)-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 Prophylaxis in patients with Chronic migraine -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 other prophylactic pharmacologic therapies, each from a different pharmacologic class (e.g., beta-blocker, anticonvulsant, tricyclic antidepressant), unless pt already tried a CGRP inhibitor indicated for chronic migraine prevention. Urinary incontinence associated with a neurological condition (e.g., spinal cord injury, multiple sclerosis) approve after a trial with at least one other

PA Criteria	Criteria Details
	pharmacologic therapy (e.g., anticholinergic medication), Overactive Bladder with symptoms of Urge Urinary Incontinence, Urgency and Frequence-approve if the patient has tried at least one other pharmacologic therapy, Spasticity, lower limb-approve, Spasticity, upper limb-approve. Pediatric Neurogenic Detrusor Overactivity (NDO)- approve if pt tried at least one other pharmacologic therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
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

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

BRONCHITOL

Products Affected

- Bronchitol

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with hypertonic saline
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
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	Cystic fibrosis-approve if the patient has passed the bronchitol tolerance test and will pre-medicate with a short-acting bronchodilator.
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	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). 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

BYLVAY

Products Affected

- Bylvay

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	PFIC- 3 months and older (initial therapy), Alagille Syndrome - 12 months and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or a physician who specializes in either progressive familial intrahepatic cholestasis (initial and continuation) for patients with PFIC or in Alagille syndrome (initial and continuation) for patients with Alagille syndrome
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	Progressive Familial Intrahepatic Cholestasis, Initial therapy-approve if the patient meets the following (i, ii, iii, and iv): i. Patient has moderate-to-severe pruritus, according to prescriber AND ii. Diagnosis of progressive familial intrahepatic cholestasis was confirmed by genetic testing demonstrating a gene mutation affiliated with progressive familial intrahepatic cholestasis AND iii. Patient does not have any of the following (a, b, or c): a) Cirrhosis OR b) Portal hypertension OR c) History of a hepatic decompensation event AND Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy. iv. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory. Progressive Familial Intrahepatic Cholestasis, continuation-approve if the patient has had a response to therapy and does not have any of the following (a, b, or c): a) Cirrhosis OR b) Portal hypertension OR c) History of a hepatic decompensation event.Note: Examples of a hepatic

PA Criteria	Criteria Details
	decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy. Alagille Syndrome, Initial therapy- approve if the patient meets the following (i, ii, iii, and iv): i. Patient has moderate-to-severe pruritus, according to prescriber AND ii. Diagnosis of Alagille syndrome was confirmed by genetic testing demonstrating a JAG1 or NOTCH2 deletion or mutation AND iii. Patient does not have any of the following (a, b, or c): a) Cirrhosis OR b) Portal hypertension OR c) History of a hepatic decompensation event - Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy. AND iv. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory. Alagille Syndrome, continuation-approve if the patient has had a response to therapy and does not have any of the following (a, b, or c): a) Cirrhosis OR b) Portal hypertension OR c) History of a hepatic decompensation event. Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BYOOVIZ

Products Affected

- Byooviz

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, diabetic retinopathy, diabetic macular edema
Part B Prerequisite	No

C1 ESTERASE INHIBITORS

Products Affected

- Berinert intravenous kit
- Cinryze
- Haegarda
- Ruconest

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 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 prophylactic therapy compared with baseline. HAE Due to C1-INH Deficiency [Type I or Type II], Treatment of Acute Attacks, 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 who has treated previous acute HAE attacks: approve if the patient has a diagnosis of HAE Type I or Type II and according to the prescriber, the patient has had a favorable clinical response.

PA Criteria	Criteria Details
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 for NSCLC
Age Restrictions	Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
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 Lenvima or sorafenib. 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 psotivie 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

PA Criteria	Criteria Details
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	1 year
Other Criteria	CLL and SLL-approve. Mantle Cell Lymphoma-approve if the patient has tried at least one systemic regimen or is not a candidate for a systemic regimen (e.g., rituximab, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, bortezomib, or lenalidomide). Marginal Zone Lymphoma-approve if patient has tried at least one systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, lenalidomide, or chlorambucil). Waldenstrom Macroglobulinamia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen (e.g., Brukinsa [zanubrutinib capsules], Imbruvica [ibrutinib tablets and capsules], rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, fludarabine, or cladribine)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma.

PA Criteria	Criteria Details
Part B Prerequisite	No

CAMZYOS

Products Affected

- Camzyos

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by a cardiologist (initial and continuation)
Coverage Duration	Initial-8 months, continuation- 1 year
Other Criteria	Obstructive hypertrophic cardiomyopathy, initial-Approve if the pt meets the following criteria (i, ii, iii and iv): i.Pt meets both of the following (a and b): a)Pt has at least 1 symptom associated w/obstructive hypertrophic cardiomyopathy (Note: examples include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise), AND b)Pt has New York Heart Association Class II or III symptoms of heart failure (Note:Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest), AND ii.Pt has left ventricular hypertrophy and meets 1 of the following (a or b): a)Pt has maximal left ventricular wall thickness greater than or equal to 15 mm, OR b)Pt has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness greater than or equal to 13 mm, AND iii.Pt has a peak left ventricular outflow tract gradient greater than or equal to 50 mmHg (at rest or after provocation [Valsalva maneuver or post exercise]), AND iv. Pt has a left ventricular ejection fraction of greater than or equal to 55 percent. Cont-Approve if pt meets ALL of the following criteria (i, ii, iii and iv):

PA Criteria	Criteria Details
	i.Pt has been established on therapy for at least 8 months (Note: pt who has received less than 8 months of therapy or who is restarting therapy is reviewed under initial therapy), AND ii.Pt meets both of the following (a and b): a)Currently or prior to starting therapy, pt has or has experienced at least 1 symptom associated with obstructive hypertrophic cardiomyopathy, AND b)Currently or prior to starting therapy, pt is in or was in New York Heart Association Class II or III heart failure, AND iii.Pt has a current left ventricular ejection fraction of greater than or equal to 50 percent, AND iv.Pt meets at least 1 of the following (a or b): a)Pt experienced a beneficial clinical response when assessed by at least 1 objective measure (Note:Examples include improved peak oxygen consumption/mixed venous oxygen tension, decreases in left ventricular outflow tract gradient, reductions in N-terminal pro-B-type natriuretic peptide levels, decreased high-sensitivity cardiac troponin I levels, reduced ventricular mass index, and/or a reduction in maximum left atrial volume index), OR b)Pt experienced stabilization or improvement in at least 1 symptom related to obstructive hypertrophic cardiomyopathy (Note:Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, ability to perform physical exercise, and/or favorable changes in the Kansas City Cardiomyopathy Questionnaire-23 (KCCQ-23) Clinical Summary Score (CSS) or Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ) Shortness of Breath domain scores.)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	1 year
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.
Part B Prerequisite	No

CARGLUMIC ACID

Products Affected

- Carbaglu
- 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-3 mo. Pt had genetic test-12 mo, 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

CERDELGA

Products Affected

- Cerdelga

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, 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 Gaucher disease or related disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient is a cytochrome P450(CYP) 2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an approved test and if the diagnosis has been established by demonstration of deficient Beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CEREZYME

Products Affected

- Cerezyme intravenous recon soln 400 unit

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic tests and lab 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	Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation
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

PA Criteria	Criteria Details
Part B Prerequisite	No

CHORIONIC GONADOTROPINS (HCG)

Products Affected

- chorionic gonadotropin, human intramuscular
- Novarel intramuscular recon soln 5,000 unit
- Pregnyl

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

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 a biologic immunomodulator. 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),

PA Criteria	Criteria Details
	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.
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	Approve through 12/31/24.
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, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz, adalimumab-adbm], Xeljanz/XR, Taltz. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. A trial of multiple adalimumab products 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, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz, adalimumab-adbm], Taltz, Stelara, Otezla, Orencia, Rinvoq, Skyrizi or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. A trial of multiple adalimumab products counts as ONE preferred product. RA initial tx, approve if the patient has tried two of the following drugs in the past:

PA Criteria	Criteria Details
	Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz, adalimumab-adbm], Orencia, Rinvoq or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. A trial of multiple adalimumab products 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, adalimumab-adbm]. Note: if the patient does not meet this requirement, a previous trial of another 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, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz, adalimumab-adbm], Skyrizi, Stelara SC, Otezla, or Taltz. A trial of Humira, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz, adalimumab-adbm 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

CINACALCET

Products Affected

- cinacalcet
- Sensipar

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

CINQAIR

Products Affected

- Cinqair

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy.
Required Medical Information	N/A
Age Restrictions	18 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 therapy, approve if the pt meets all of the following criteria: 1)must have blood eosinophil count of greater than or equal to 400 cells per microliter within the previous 4 wks (prior to treatment with Cinqair or another monoclonal antibody therapy that may lower blood eosinophil level), AND 2) pt has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid and at least one additional asthma controller or asthma maintenance medication (Examples-LAMA, LABA, leukotrienes, monoclonal antibody), AND 3) Pt's asthma is uncontrolled or was uncontrolled prior to starting Cinqair or another monoclonal antibody therapy for asthma as defined by ONE of the following: pt experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, or pt experienced one or more asthma exacerbation requiring hospitalization, an urgent care visit or an ER visit in the previous year, or pt has a FEV1 less than 80 percent predicted, or pt has an FEV1/FVC less than 0.80, or patient's asthma worsens upon tapering of oral (systemic) corticosteroid therapy.Continuation therapy, approve if the pt meets all of the following criteria: 1) pt has responded to Cinqair therapy as determined by the

PA Criteria	Criteria Details
	prescribing physician (eg, decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, ER/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy), AND 2) pt continues to receive therapy with an inhaled corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CLOBAZAM

Products Affected

- clobazam oral suspension
- clobazam oral tablet
- Onfi oral suspension
- Onfi 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 and/or is concomitantly receiving one of the following: lamotrigine, topiramate, rufinamide, felbamate, Fintepla, Epidiolex or valproic acid. 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

PA Criteria	Criteria Details
	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 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	18 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	1 year
Other Criteria	Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma - approve if the patient has tried one systemic regimen (e.g., Imbruvica (ibrutinib capsules, tablets and oral solution), Venclexta (venetoclax tablets), rituximab, Gazyva (obinutuzumab intravenous infusion), chlorambucil, fludarabine, cyclophosphamide, bendamustine, high-dose methylprednisolone, Campath (alemtuzumab intravenous infusion), Calquence (acalabrutinib capsules), Brukinsa (zanubrutinib capsules), or Arzerra (ofatumumab intravenous infusion). 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

CORTROPHIN

Products Affected

- Cortrophin Gel

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous medications tried and response
Age Restrictions	Acute MS exacerbations-adults
Prescriber Restrictions	MS-prescr/consult w/neuro/phys specializes MS. RA, JIA/JRA, AS, PsA, SLE, Syst Dermat, acute gouty arthritis-prescr/consult w/rheum. Severe Erythema Multiforme, severe psoriasis-prescr/consult w/derm. Serum Sickness, AD-prescr/consult w/allergist. Severe acute/chronic allergic/inflamm involving eye/adnexa, allergic conjunctivitis-prescr/consult w/ophthalmol. Symptomatic Sarcoidosis-prescr/consult w/pulm or cardio. Nephrotic Syndrome-prescr/consult w/nephro
Coverage Duration	1 month
Other Criteria	For acute MS exacerbation, approve if Cortrophin is NOT being used as pulse therapy on a monthly basis. For all other FDA approved diagnoses, approve if the patient has tried a systemic corticosteroid for the current condition and has experienced a severe adverse effect or treatment failure with the corticosteroid (e.g., a psychotic reaction).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COSELA

Products Affected

- Cosela

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	6 months
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. SCLC-approve if the patient has extensive-stage disease, the medication is used to decrease the incidence of chemotherapy-induced myelosuppression and the patient will be receiving platinum (carboplatin or cisplatin) and etoposide-containing chemotherapy regimen or patient will be receiving topotecan-containing regimen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COSENTYX

Products Affected

- Cosentyx (2 Syringes)
- Cosentyx Pen
- Cosentyx Pen (2 Pens)
- Cosentyx subcutaneous syringe 150 mg/mL, 75 mg/0.5 mL
- Cosentyx UnoReady Pen

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis and previous medications use
Age Restrictions	PP-6 yr and older.AS/Spondy/HS initial - 18 years of age and older. PsA-2 years and older. Enthesitis-4 years and older
Prescriber Restrictions	PP initial-presc/consult derm. PsA initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS/spondylo/enthesitis initial- by or in consultation with rheumatologist. HS initial - by or in consult w/ dermatologist
Coverage Duration	Approve through 12/31/24.
Other Criteria	PP initial (patients 18 years and older) -approve if the patient has tried TWO of the following: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Skyrizi, Stelara SC, Otezla or Taltz. A trial of multiple adalimumab products counts as ONE preferred product. PsA (patients 18 years and older) initial-approve if the patient has tried TWO of the following: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Skyrizi, Stelara SC, Otezla, Orencia, Xeljanz/XR, Rinvoq or Taltz. (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the try TWO requirement: Cimzia, an infliximab product, golimumab SC/IV, or a non-preferred adalimumab product. A trial of multiple adalimumab products counts as

PA Criteria	Criteria Details
	ONE preferred product. AS-approve if the patient has tried TWO of the following-Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Xeljanz/XR or Taltz. Note: if the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count. A trial of multiple adalimumab products counts as ONE preferred product. Non-radiographic axial spondyloarthritis-approve if the patient has tried Taltz. Enthesitis-related arthritis-approve. Hidradenitis Suppurativa - approve if the patient has tried an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm]. Note: if the patient does not meet this requirement, a trial of a non-preferred adalimumab product will also count. continuation - patient must have responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COSENTYX IV

Products Affected

- Cosentyx intravenous

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs)
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	PsA initial - Prescribed by or in consultation with a dermatologist or rheumatologist. AS/Non-radio Axial Spondy-Prescribed by or in consultation with a rheumatologist.
Coverage Duration	1 year
Other Criteria	PsA initial-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, Orencia, Xeljanz/XR, Rinvoq or Taltz. (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the try TWO requirement: Cimzia, an infliximab product, golimumab SC/IV, Amjevita (NDCs starting with 72511) or another non-preferred adalimumab product. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product) [documentation required]. AS, initial-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 or Taltz [documentation required]. 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

PA Criteria	Criteria Details
	trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product. Non-radiographic axial spondyloarthritis-approve if the patient has tried Taltz [documentation required]. Continuation - patient must have responded, as determined by the prescriber [documentation to demonstrate response to treatment required]. Note to Pharmacist Reviewer: documentation submitted must confirm response. Please note-all cases are reviewed with a UM Pharmacist prior to approval.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	1 year
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 one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma OR b) isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma OR iii. Melanoma with brain metastases AND medication with 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 (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease AND C) Patient has BRAF V600 mutation-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Central Nervous System Cancer
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

CRINONE GEL

Products Affected

- Crinone vaginal gel 8 %

PA Criteria	Criteria Details
Exclusion Criteria	Use in patients to supplement or replace progesterone in the management of infertility.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Secondary amenorrhea, 12 months.Support of an established pregnancy, 9 months.
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Support of an established pregnancy
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

PA Criteria	Criteria Details
	age and gender. Cont-approve if the patient is continuing to derive benefit as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CYSTEAMINE (OPHTHALMIC)

Products Affected

- Cystadrops
- 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
- Procysbi

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

- Ampyra
- 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

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	1 year
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

DAYBUE

Products Affected

- Daybue

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Rett Syndrome-approve if the patient meets the following (A and B): A) Patient has a pathogenic mutation in the MECP2 gene, AND B) Patient has classic/typical Rett syndrome, according to the Rett Syndrome Diagnostic Criteria
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DEFERASIROX

Products Affected

- deferasirox
- Exjade
- Jadenu
- Jadenu Sprinkle

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
- Ferriprox
- Ferriprox (2 times a day)

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

DESOXYN

Products Affected

- methamphetamine

PA Criteria	Criteria Details
Exclusion Criteria	Weight loss.
Required Medical Information	Diagnosis
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

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

DICLOFENAC (TOPICAL)

Products Affected

- diclofenac epolamine
- Flector
- Licart

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 mos.
Other Criteria	Patients must try a generic oral NSAID or generic diclofenac 1 percent gel.
Indications	All Medically-accepted 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
- Tecfidera 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	If the patient is requesting brand name Tecfidera, approve if the patient meets the following (a and b): a) Patient has tried generic dimethyl fumarate delayed-release capsules AND b) Patient cannot continue to use generic dimethyl fumarate delayed-release capsules due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DOJOLVI

Products Affected

- Dojolvi

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medium-chain triglyceride products
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist or a physician who specializes in the management of long-chain fatty acid oxidation disorders
Coverage Duration	1 year
Other Criteria	Long-Chain Fatty Acid Oxidation Disorders-Approve if the patient has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder based on at least TWO of the following (TWO of i, ii, or iii): i. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma OR ii. Enzyme activity assay (in cultured fibroblasts or lymphocytes) below the lower limit of the normal reference range for the reporting laboratory OR iii. Genetic testing demonstrating pathogenic mutation in a gene associated with long-chain fatty acid oxidation disorders
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

DROXIDOPA

Products Affected

- droxidopa
- Northera

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Medication history (as described in Other Criteria field)
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. For all covered diagnoses, if the request is for brand name Northera-the patient is required to have tried generic droxidopa tablets AND cannot use the generic product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DUAL OREXIN RECEPTOR ANTAGONIST

Products Affected

- Belsomra
- Dayvigo
- Quviviq

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	Treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance-approve if the patient has tried two of the following: generic doxepin, generic eszopiclone, generic zaleplon, generic zolpidem/ER - oral/sublingual or generic ramelteon.
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 (i.e., Adbry, Cinqair, Fasenra, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical].
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

PA Criteria	Criteria Details
	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 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

DURYSTA

Products Affected

- Durysta

PA Criteria	Criteria Details
Exclusion Criteria	Re-treatment of previously treated eyes
Required Medical Information	Diagnosis
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist
Coverage Duration	Approve one time use for each treated eye (i.e., one implant per treated eye)
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DYSPORT

Products Affected

- Dysport

PA Criteria	Criteria Details
Exclusion Criteria	Use in the management of cosmetic uses.
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	Spasticity (other than limb) and blepharospasm
Part B Prerequisite	No

EGRIFTA

Products Affected

- Egrifta SV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of human immunodeficiency virus (HIV) infection (initial therapy)
Coverage Duration	6 months initial, 1 year continuation
Other Criteria	Lipodystrophy in HIV-infected patients-Initial-approve if Egrifta is being prescribed for the reduction of excess abdominal fat and the patient meets one of the following-If male, waist circumference is greater than or equal to 95 cm (37.4 in) and waist-to-hip ratio is greater than or equal to 0.94 OR If female, waist circumference is greater than or equal to 94 cm (37 in) and waist-to-hip ratio is greater than or equal to 0.88 AND the patient has been stable on anti-retroviral regimen for at least 8 weeks. Continuation-approve if the patient has responded to Egrifta therapy.
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

ELELYSO

Products Affected

- Elelyso

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic tests and lab results
Age Restrictions	4 years and older
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	Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ELFABRIO

Products Affected

- Elfabrio

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Galafold (migalastat oral capsules). Concurrent Use with Fabrazyme (agalsidase beta intravenous infusion).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
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	Fabry disease-approve if the diagnosis is established by one of the following: patient has a laboratory test demonstrating deficient alpha-galactosidase A activity in leukocytes or fibroblasts OR patient has a molecular genetic test demonstrating pathogenic mutations in the galactosidase alpha gene.
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

ELYXYB

Products Affected

- Elyxyb

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 if the patient has tried at least one triptan therapy or has a contraindication to triptans.
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

EMFLAZA

Products Affected

- deflazacort
- Emflaza

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	2 years of age and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders (initial and continuation therapy)
Coverage Duration	1 year
Other Criteria	Initial therapy-approve if the patient's diagnosis is confirmed by genetic testing with a confirmed pathogenic or likely pathogenic variant in the dystrophin gene or muscle biopsy showing the absence of, or marked decrease in, dystrophin protein. Continuation-approve if the patient has responded to or continues to have improvement or benefit from therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EMGALITY

Products Affected

- Emgality Pen
- Emgality Syringe subcutaneous syringe 120 mg/mL, 300 mg/3 mL (100 mg/mL x 3)

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.

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

EMPAVELI

Products Affected

- Empaveli

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Soliris or Ultomiris
Required Medical Information	Diagnosis, test results
Age Restrictions	PNH-18 years and older (initial therapy and continuation)
Prescriber Restrictions	PNH-prescribed by or in consultation with a hematologist (initial therapy and continuation)
Coverage Duration	PNH-initial 4 months, cont-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Paroxysmal Nocturnal Hemoglobinuria (PNH)-Initial therapy-Approve if diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages AND for a patient transitioning to Empaveli from Soliris (eculizumab intravenous infusion), the prescriber attests that Soliris will be discontinued 4 weeks after starting Empaveli. Continuation-approve if the patient is continuing to derive benefit (e.g., stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis).
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. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist.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	Approve through 12/31/24.
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)

PA Criteria	Criteria Details
	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) 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

ENDARI

Products Affected

- Endari

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	Greater than or equal to 5 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (e.g., a hematologist)
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENHERTU

Products Affected

- Enhertu

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-approve if the patient has tried at least one prior regimen, has recurrent or metastatic breast cancer and has HER2 positive disease or HER 2 immunohistochemistry (IHC) 1+ or IHC 2+ and in situ hybridization (ISH) negative disease and meets one of the following: has HR positive disease and is refractory to endocrine therapy or patient has HR negative disease. Colon or Rectal Cancer-approve if the patient has human epidermal growth factor receptor 2 (HER2)-amplified disease, has unresectable, advanced, or metastatic disease, has wild-type RAS and BRAF disease AND Patient has tried chemotherapy. Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has unresectable or metastatic desease, the disease has activating human epidermal growth factor receptor 2 (HER2)-mutations and the patient has tried at least one prior systmic therapy. Gastric or gastroesophageal junction cancer-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease and the patient has received at least one prior trastuzumab-based regimen. Esophageal

PA Criteria	Criteria Details
	cancer-approve if the patient has HER-2 positive disease and has received at least one prior trastuzumab-based regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Colon or Rectal cancer, esophageal cancer
Part B Prerequisite	No

ENJAYMO

Products Affected

- Enjaymo

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 hematologist
Coverage Duration	1 year
Other Criteria	Cold Agglutinin Disease-approve if the patient meets the following criteria: A) Patient weighs greater than or equal to 39 kg, AND B) Patient has a history of at least one sign or symptom associated with cold agglutinin disease, AND Note: Examples include symptomatic anemia (e.g., anemia associated with fatigue, weakness, shortness of breath, heart palpitations, lightheadedness, chest pain), acrocyanosis, Raynaud's syndrome, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event (e.g., thrombosis). C) According to the prescriber, the patient has evidence of chronic hemolysis, AND D) Patient meets the following diagnostic criteria (i and ii): i. Direct antibody test strongly positive for C3d and negative or only weakly positive for immunoglobulin G, AND ii. Cold agglutinin antibody titer greater than or equal to 64 at 4 degrees C (approximately 40 degrees F), AND E) At baseline (prior to the initiation of Enjaymo), patient meets both of the following (i and ii): i. Hemoglobin less than or equal to 10 g/dL, AND ii. Total bilirubin above the upper limit of normal, based on the reference range for the reporting laboratory, AND F) According to the prescriber, secondary causes of cold agglutinin syndrome have been excluded Note: Examples of secondary

PA Criteria	Criteria Details
	causes of cold agglutinin syndrome include infection, rheumatologic diseases, and active hematologic malignancies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENSPRYNG

Products Affected

- Enspryng

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Soliris, rituximab or Uplizna
Required Medical Information	Diagnosis, test results (all as described in Other Criteria field)
Age Restrictions	NMOSD-18 years and older (initial and continuation)
Prescriber Restrictions	NMOSD-prescribed by or in consultation with a neurologist or ophthalmologist (initial and continuation)
Coverage Duration	NMOSD-initial-1 year, cont-1 year
Other Criteria	Neuromyelitis Optica Spectrum Disorder-initial therapy-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and the patient has a history of at least 1 relapse in the last 12 months or two relapses in the last 2 years. Continuation- approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and the patient has had a clinical benefit from the use of Enspryng.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENTADFI

Products Affected

- Entadfi

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

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

PA Criteria	Criteria Details
	example, decreased stool frequency or rectal bleeding), as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENTYVIO PEN

Products Affected

- Entyvio Pen

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	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial)
Coverage Duration	Approve through 12/31/24
Other Criteria	Ulcerative Colitis, initial therapy with Entyvio SC: approve if the patient meets (A and B): (A) the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months of initiating therapy with Entyvio subcutaneous, (B) patient meets (i or ii): (i): the patient has had a trial of TWO of the following: Stelara, Entyvio IV, Remicade, or an adalimumab product [i.e., Humira, Cyltezo, adalimumab-adbm, Hyrimoz (NDCs starting with -61314), adalimumab-adaz]. Trials of Omvoh IV/SC, Zymfentra or a Non-Preferred IV infliximab product, Simponi SC, or a Non-Preferred adalimumab product will also count. Trials of multiple adalimumab products count as ONE preferred product. OR (ii) the patient has already started on Entyvio IV or is currently undergoing induction therapy with Entyvio IV. Ulcerative colitis, continuation of therapy with Entyvio SC: approve if the patient has had a response to therapy.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
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 antiseizuredrugs 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 antiseizure drugs.Tuberous Sclerosis Complex-approve if the patient has tried or is concomitantly receiving at least two other antiseizure 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.

PA Criteria	Criteria Details
Part B Prerequisite	No

EPOETIN ALFA

Products Affected

- Epogen injection solution 10,000 unit/mL, 2,000 unit/mL, 20,000 unit/2 mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL
- 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 as a non-curative treatment 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-1 yr, 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. For all covered uses, if the request is for Epogen, then the patient is required to try Procrit or Retacrit first. Anemia in patients with chronic renal failure on dialysis - deny under

PA Criteria	Criteria Details
	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
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 1 year.
Other Criteria	Basal cell carcinoma, locally advanced-patients new to therapy-approve if the patient has tried Odomzo. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has medulloblastoma, 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 (this includes primary or recurrent nodal metastases and distant metastases)-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	1 year
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
- Tarceva 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 1 year.
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. 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 at least 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.

PA Criteria	Criteria Details
Part B Prerequisite	No

EVEKEO

Products Affected

- amphetamine sulfate
- Evekeo
- Evekeo ODT

PA Criteria	Criteria Details
Exclusion Criteria	Weight loss.
Required Medical Information	Diagnosis
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

EVENITY

Products Affected

- Evenity

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis (e.g., oral or IV bisphosphonates, Prolia, Forteo, Tymlos, calcitonin nasal spray) except calcium and Vitamin D
Required Medical Information	Diagnosis, medications that have been tried in the past, other medications that will be used in combination
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months of therapy per course of treatment.
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 patient has had 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), or 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 in which IV bisphosphonate therapy may be warranted (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of

PA Criteria	Criteria Details
	the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid) OR patient has severe renal impairment (creatinine clearance less than 35 mL/min), chronic kidney disease or has had an osteoporotic fracture or a fragility fracture.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EVEROLIMUS

Products Affected

- Afinitor
- Afinitor Disperz oral tablet for suspension 2 mg, 3 mg, 5 mg
- 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, renal angiomyolipoma or partial onset seizures-18 years and older.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
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 postmenopausal woman or man OR ii.pt is pre/perimenopausal woman AND receiving ovarian suppression/ablation with GnRH agonist, or 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 w/exemestane and pt meets 1 of following:pt is male and receiving a GnRH analog or pt is 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 req therapeutic intervention but cannot be

PA Criteria	Criteria Details
	curatively resected.Thymomas and Thymic Carcinomas-approve if pt has tried chemo or cannot tolerate chemo.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 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. 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, CNS lesions, multisystem disease or pulmonary disease.Pt must also have PIK3CA mutation.For all covered diagnoses, if the request is for brand Afinitor-pt is required to have tried generic everolimus tablets AND cannot use the generic product due to formulation diff in the inactive ingredient(s)[e.g., difference in dyes, fillers, preservatives] between Brand and generic product which would result in a significant allergy or serious adverse reaction.Uterine Sarcoma-approve if pt has advanced, recurrent, metastatic, or inoperable disease, AND has perivascular epithelioid cell tumor (PEComa), AND has tried at least 1 systemic regimen.Note: Examples of include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine.
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), men with breast cancer, Pre-peri-menopausal women with breast cancer, Histiocytic Neoplasm, uterine sarcoma
Part B Prerequisite	No

EVKEEZA

Products Affected

- Evkeeza

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
Age Restrictions	5 years 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	HoFH-approve if pt meets (A, B, and C): A)Pt meets 1 of the following (i, ii or iii): i.Pt had genetic confirmation of 2 mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus OR ii.Pt has an untreated LDL-C level greater than 500 mg/dL AND meets one of the following (a or b):a)Pt had clinical manifestations of HoFH b/f age 10 yrs OR Note:Clinical manifestations of HoFH are cutaneous xanthomas, tendon xanthomas, acrus cornea, tuberous xanthomas, or xanthelasma. b)Both parents of pt had untreated LDL-C levels or total cholesterol (TC) levels consistent with HeFH OR Note: example of HeFH in both parents would be if both had an untreated LDL-C level greater than or equal to 190 mg/dL and/or an untreated TC level greater than 250 mg/dL. iii)Pt has a treated LDL-C level greater than or equal to 300 mg/dL AND meets one of the following (a or b): a)Pt had clinical manifestations of HoFH b/f age 10 yrs OR b)Both parents of pt had untreated LDL-C levels or TC levels consistent with HeFH AND B)Pt meets one of the following (i or ii): i.Pt

PA Criteria	Criteria Details
	meets all of the following criteria (a and b): a)Pt has tried one high-intensity statin therapy (i.e., atorva greater than or equal to 40 mg daily, rosuva greater than or equal to 20 mg daily [as a single-entity or as a combination product]) AND b)LDL-C level after this regimen remains greater than or equal to 70 mg/dL OR ii.Pt is determined to be statin intol by meeting one of the following criteria (a or b): a) Pt experienced statin-related rhabdomyolysis OR Note: Rhabdo is statin-induced muscle breakdown associated with markedly elevated creatine kinase levels (at least 10 times the upper limit of normal), along with evidence of end organ damage which can include signs of acute renal injury (noted by substantial increases in serum creatinine [Scr] levels [a greater than or equal to 0.5 mg/dL increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]) OR b)Pt meets all of the following criteria [(1), (2), and (3)]: (1)Pt experienced skeletal-related muscle symptoms AND Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, or tenderness). (2)symptoms occurred while receiving separate trials of both atorva and rosuva AND (3)When receiving separate trials of both atorva and rosuva the skeletal-related muscle symptoms resolved upon d/c of each respective statin therapy (atorva and rosuva) AND C)Pt meets one of the following (i, ii or iii): i) Pt meets both of the following (a and b): a)Pt has tried a PCSK9 inhibitor for greater than or equal to 8 continuous weeks AND b)LDL-C level after this PCSK9 inhibitor therapy remains greater than or equal to 70 mg/dL OR ii)Pt is known to have two LDL-receptor negative alleles or iii)patient is 5-9 years of age.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EVRYSDI

Products Affected

- Evrysdi

PA Criteria	Criteria Details
Exclusion Criteria	Pregnant patients, female patients not utilizing effective contraception during treatment and for 1 month after the last dose of Evrysdi
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a physician who has consulted with or who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders (initial and continuation)
Coverage Duration	4 months
Other Criteria	Spinal Muscular Atrophy, Initial Treatment - Approve if the patient has baseline motor ability assessment that suggests spinal muscular atrophy (based on age, motor ability, and development) is provided from one of the following exams: (a, b, c, d, e, f, or g): a) Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [Item 22], OR b) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), OR c) Hammersmith Functional Motor Scale Expanded (HFMSE), OR d) Hammersmith Infant Neurological Exam Part 2 (HINE-2), OR e) Motor Function Measure-32 Items (MFM-32), OR f) Revised Upper Limb Module (RULM) test, OR g) World Health Organization motor milestone scale AND if the patient has had a genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene reported as at least one of the following: homozygous deletion, homozygous mutation, or compound heterozygous mutation AND the patient meets both of the following criteria (a and b): a) has two to four survival motor neuron 2 (SMN2) gene copies AND b) the patient has objective signs consistent with spinal

PA Criteria	Criteria Details
	muscular atrophy Types 1, 2, or 3 AND for patients who are currently receiving or have received prior treatment with a survival motor neuron 2 (SMN2)-directed antisense oligonucleotide, the prescriber attests that further therapy with this product will be discontinued. Patients currently receiving Evrysdi - approve if the patient meets the requirements for initial therapy AND has responded to Evrysdi and continues to have benefit from ongoing Evrysdi therapy by the most recent (within the past 4 months) physician monitoring/assessment tool OR patient must have had a positive clinical response from pretreatment baseline (i.e., within the past 4 months) from one of the following exams: (a, b, c, d, e, f, or g): a) Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [Item 22], OR b) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), OR c) Hammersmith Functional Motor Scale Expanded (HFMSE), OR d) Hammersmith Infant Neurological Exam Part 2 (HINE-2), OR e) Motor Function Measure-32 Items (MFM-32), OR f) Revised Upper Limb Module (RULM) test, OR g) World Health Organization motor milestone scale.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	1 year
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

EXONDYS 51

Products Affected

- Exondys-51

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	DMD- patient has a confirmed mutation of the DMD gene that is amenable to exon 51 skipping
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

EYLEA HD

Products Affected

- Eylea HD

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	For all covered indications, the patient must have a trial of Eylea (not HD) prior to approval of Eylea HD.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EYSUVIS

Products Affected

- Eysuvis

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

FABHALTA

Products Affected

- Fabhalta

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another complement inhibitor
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with a hematologist (initial/continuation)
Coverage Duration	Initial-4 months, continuation-1 year
Other Criteria	Paroxysmal nocturnal hemoglobinuria, initial-Approve if paroxysmal nocturnal hemoglobinuria diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins on at least two cell lineages. Paroxysmal nocturnal hemoglobinuria, continuation-Approve if the patient is continuing to derive benefit from the requested medication. Note: Examples of benefit include increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis.
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 another monoclonal antibody therapy.
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 or within 6 weeks prior to treatment with Fasenra or another monoclonal antibody therapy that may lower blood eosinophil levels AND meet both of the following criteria: 1) Patient has received combination therapy with an inhaled corticosteroid AND at least one additional asthma controller or asthma maintenance medication (Examples: LABA, LAMA, leukotrienes, monoclonal antibodies for asthma), AND 2) Patient's asthma is uncontrolled or was uncontrolled prior to receiving Fasenra or another monoclnal antibody therapy for asthma 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, an urgent care visit 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. Continuation - The patient has responded to Fasenra therapy as determined by the

PA Criteria	Criteria Details
	prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy) AND patient continues to receive therapy with an inhaled corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FILSPARI

Products Affected

- Filspari

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with any renin-angiotensin-aldosterone antagonists (e.g., angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists, or aliskiren
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with an nephrologist (initial/continuation)
Coverage Duration	Initial-9 months, continuation-1 year
Other Criteria	Primary Immunoglobulin A Nephropathy, initial-approve if the diagnosis has been confirmed by biopsy AND patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73 m2 AND patient is at high risk of disease progression, defined by meeting the following criteria (a and b): a) Proteinuria greater than 1.0 g/day or urine protein-to-creatinine ratio greater than or equal to 1.5 g/g, AND b) patient has received a maximally tolerated dose of an angiotensin converting enzyme inhibitor or angiotensin receptor blocker for greater than or equal to 12 weeks prior to starting Filspari. Primary Immunoglobulin A Nephropathy, continuation-approve if the diagnosis has been confirmed by biopsy, the patient has had a response to therapy, and the patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73 m2.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

FINGOLIMOD

Products Affected

- fingolimod
- Gilenya

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	10 years and older
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
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

FIRMAGON

Products Affected

- Firmagon kit w diluent syringe

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 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. Patients new to therapy, are required to try Eligard or Orgovyx prior to approval of Firmagon.
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 1 year.
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

FRUZAQLA

Products Affected

- Fruzaqla oral capsule 1 mg, 5 mg

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	Colon cancer, rectal cancer, or appendiceal cancer-Approve if the patient meets the following (A and B): A.Patient has advanced or metastatic disease, AND B.Patient has previously been treated with the following (i, ii, and iii): i.Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine. AND ii.An anti-vascular endothelial growth factor (VEGF) agent, Note: Examples of anti-VEGF agents include bevacizumab. AND iii. If the tumor is RAS wild-type (KRAS wild-type and NRAS wild-type) [that is, the tumor or metastases are KRAS and NRAS mutation negative], the patient meets ONE of the following (a or b): a.According to the prescriber, anti-epidermal growth factor receptor (EGFR) therapy is NOT medically appropriate, OR b. The patient has received an anti-EGFR therapy. Note: Examples of anti-EGFR therapy includes Erbitux (cetuximab intravenous infusion) and Vectibix (panitumumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Appendiceal cancer
Part B Prerequisite	No

FULPHILA

Products Affected

- Fulphila

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-30 days.
Other Criteria	Cancer patients receiving chemotherapy, approve if - the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia 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. Patients are required to try Ziextenzo and Nyvepria prior to approval of Fulphila.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
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

FYLNETRA

Products Affected

- Fylnetra

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% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia 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. Patients are required to try Ziextenzo and Nyvepria prior to approval of Fylnetra.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No

GALAFOLD

Products Affected

- Galafold

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	16 years and older
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, nephrologist, or a physician who specializes in the treatment of Fabry disease
Coverage Duration	1 year
Other Criteria	Approve if the patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GAMIFANT

Products Affected

- Gamifant

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic test results, lab results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, oncologist, immunologist, transplant specialist, or physician who specializes in hemophagocytic lymphohistiocytosis or related disorders
Coverage Duration	6 months
Other Criteria	Hemophagocytic Lymphohistiocytosis, Primary. Patients must meet all of the following Criteria: i. The patient has a diagnosis of hemophagocytic lymphohistiocytosis determined by molecular genetic diagnosis consistent with hemophagocytic lymphohistiocytosis OR prior to treatment, the patient meets at least FIVE of the following diagnostic criteria at baseline (FIVE of: a, b, c, d, e, f, g, or h): a) Fever greater than or equal to 38.5 Celsius, b) Splenomegaly, c) Cytopenias defined as at least TWO of the following (1, 2, or 3): 1) Hemoglobin less than 9 g/dL (or less than 10 g/dL in infants less than 4 weeks of age) OR 2) Platelets less than 100 x 109/L OR 3) Neutrophils less than 1.0 x 109/L OR d) Fasting triglycerides greater than or equal to 265 mg/dL OR fibrinogen less than or equal to 1.5 g/L OR e) Hemophagocytosis in bone marrow, spleen, or lymph nodes OR f) Low or absent natural killer cell activity (according to local laboratory reference) OR g) Ferritin greater than or equal to 500 mcg/L OR h) Soluble CD25 (i.e., soluble interleukin-2 receptor) greater than or equal to 2,400 U/mL

PA Criteria	Criteria Details
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. thyroid cancer-12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
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. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion-positive disease or RET-mutation positive disease and has anaplastic thyroid cancer or the patient has medullary thyroid cancer or the disease is radioactive iodine-refractory.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Medullary Thyroid Cancer
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 1 year.
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. (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	Head and neck cancer
Part B Prerequisite	No

GIVLAARI

Products Affected

- Givlaari

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 gastroenterologist, hepatologist, or a physician who specializes in acute hepatic porphyria.
Coverage Duration	1 year
Other Criteria	Acute hepatic porphyria-approve if patient demonstrated clinical features associated with acute hepatic porphyria AND the patient has elevated urinary aminolevulinic acid (ALA) greater than the upper limit of normal or elevated urinary porphobilinogen (PBG) greater than the upper limit of normal and prior to starting treatment with Givlaari, the patient has a history of one porphyria attack in the last 6 months that required a hospitalization, urgent healthcare visit or intravenous hemin administration at home.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GLATIRAMER

Products Affected

- Copaxone subcutaneous syringe 20 mg/mL, 40 mg/mL
- 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	If the patient is requesting brand name Copaxone-approve if the patient has tried generic glatiramer and cannot continue to use generic glatiramer due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction.
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	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	Approve Victoza if the patient is less than 18 years of age and has tried Trulicity. Approve Victoza if the patient has tried Ozempic and Trulicity. If the patient is requesting Victoza and they do not meet the scenarios listed above, the patient must have a trial of TWO of the following: Byetta, Trulicity, Bydureon, Bydureon BCise, Ozempic, Rybelsus or Mounjaro prior to approval.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GNRH AGONIST IMPLANTS

Products Affected

- Supprelin LA
- 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

GOCOVRI

Products Affected

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

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

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

GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

Products Affected

- Eligard
- Eligard (3 month)
- Eligard (4 month)
- Eligard (6 month)
- Fensolvi
- leuprolide (3 month)
- 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)
- Triptodur

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 3 mo.All other=12 mo
Other Criteria	If the patient is requesting Lupron 7.5 mg, 22.5 mg, 30mg or 45 mg for a diganosis of prostate cancer, patients are required to try Orgovyx or Eligard prior to approval.
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

PA Criteria	Criteria Details
Part B Prerequisite	No

GRALISE/HORIZANT/LYRICA CR

Products Affected

- gabapentin oral tablet extended release 24 hr 300 mg, 600 mg
- Gralise oral tablet extended release 24 hr 300 mg, 450 mg, 600 mg, 750 mg, 900 mg
- Horizant oral tablet extended release 300 mg, 600 mg
- Lyrica CR oral tablet extended release 24 hr 165 mg, 330 mg, 82.5 mg
- pregabalin oral tablet extended release 24 hr 165 mg, 330 mg, 82.5 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 12 months.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GRANIX

Products Affected

- Granix

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Cancer patient receiving chemo-Prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist or physician that specializes in transplantation. Myelodysplastic syndromes-prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	PBPC-1 month, MDS-3 months, All others-6 months
Other Criteria	Cancer patients receiving Myelosuppressive Chemotherapy-Must meet ONE of the following - 1. be receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen) 2. be receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (e.g., at least 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, HIV infection) 3. have had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a CSF (e.g., filgrastim products, pegfilgrastim products, or Leukine) and a reduced dose or frequency of chemotherapy may compromise treatment OR 4. has received chemotherapy has febrile

PA Criteria	Criteria Details
	neutropenia and has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the prescribing physician (e.g., sepsis syndrome, older than 65 years, severe neutropenia - ANC less than 100 cells/mm3, neutropenia expected to be more than 10 days in duration, invasive fungal infection, other clinically documented infections, or prior episode of febrile neutropenia). Patients are required to try Zarxio and Nivestym prior to approval of Granix unless patient has initiated therapy with Granix and requires additional medication to complete the current cycle of chemotherapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing peripheral blood progenitor cell (PBPC) Collection and Therapy. Myelodysplastic syndromes.
Part B Prerequisite	No

GROWTH HORMONES

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	HIV 1.wasting/cachexia due to malabsorption, opportunistic infx, depression and other causes which have been addressed prior to starting tx, 2.on antiretroviral or HAART for more than 30 days and will cont throughout Serostim tx, 3.not being used for alternations in body fat distribution (abdom girth, liopdystrophy, buffalo hump, excess abdm fat), AND 4. unintentional wt loss greater than 10 percent from baseline, wt less than 90 percent of lower limit of IBW, or BMI less than or equal to 20 kg/m2. Cont-must be off therapy for 1 month.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 multiple pituitary deficiencies and pt has 3 or more pituitary hormone deficiencies

PA Criteria	Criteria Details
	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 and HIV wasting/cachexia 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, HIV 6 months, others 12 mos
Other Criteria	GHD initial in adults and adolescents 1. endocrine must certify not prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalmic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or SAH, AND 3. meets one of the following - A. has known mutations, embryonic lesions, congenital or genetic defects or structural hypothalmic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, age and gender adjusted IGF1 below the lower limits of the normal reference range, 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 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, Macrilen peak less than 2.8 ng/ml if BMI is less than or equal to 40 AND if a transitional adoles must be off tx for at least one month before retesting. Cont tx - endocrine must certify not 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 ht velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal

PA Criteria	Criteria Details
	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 ht less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, ht less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth wt/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/adolescent, 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. If requesting Genotropin, Humatrope, Nutropin, Norditropin or Zomacton must have tried Omnitrope prior to approval.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Short bowel syndrome (all products except Serostim)
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
- Hetlioz LQ
- 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-3 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

- Ativan injection
- Ativan oral tablet 0.5 mg, 1 mg, 2 mg
- 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
- Loreev XR oral capsule,extended release 24hr 1 mg, 1.5 mg, 2 mg, 3 mg
- Valium

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 or Loreev XR 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.

PA Criteria	Criteria Details
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
- Fexmid

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 promethazine, authorize use without a previous drug trial for all FDA-approved indications other than emesis, including cancer/chemo-related emesis. For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. For the treatment of non-cancer/chemo related emesis, approve promethazine hydrochloride if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant) for the current condition. Approve hydroxyzine hydrochloride if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval of promethazine and hydroxyzine, approve if the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
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

- Activella
- Amabelz
- Angeliq
- Bijuva
- Climara
- Climara Pro
- CombiPatch
- Divigel transdermal gel in packet 0.25 mg/0.25 gram (0.1 %), 0.5 mg/0.5 gram (0.1 %), 0.75 mg/0.75 gram (0.1%), 1 mg/gram (0.1 %), 1.25 mg/1.25 gram (0.1 %)
- Dotti
- Elestrin
- Estrace oral
- estradiol oral
- estradiol transdermal gel in packet 0.25 mg/0.25 gram (0.1 %), 0.5 mg/0.5 gram (0.1 %), 0.75 mg/0.75 gram (0.1%), 1 mg/gram (0.1 %), 1.25 mg/1.25 gram (0.1 %)
- estradiol transdermal patch semiweekly
- estradiol transdermal patch weekly
- estradiol-norethindrone acet
- Evamist
- Fyavolv
- Jinteli
- Lyllana
- Menest
- Menostar
- Mimvey
- Minivelle
- norethindrone ac-eth estradiol oral tablet 0.5-2.5 mg-mcg, 1-5 mg-mcg
- Prefest
- Vivelle-Dot

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Previous medication use
Age Restrictions	Patients aged 65 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months

PA Criteria	Criteria Details
Other Criteria	For the treatment of Vulvar Vaginal Atrophy, approve if the patient has had a trial of one of the following for vulvar vaginal atrophy (brand or generic): Estradiol Vaginal Cream, Premarin Vaginal Cream, Estring, Imvexxy 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, risedronate 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 (PREFERRED NDCS STARTING WITH 00074) subcutaneous syringe kit 40 mg/0.8 mL
- Humira Pen (PREFERRED NDCS STARTING WITH 00074)
- Humira Pen Crohns-UC-HS Start (PREFERRED NDCS STARTING WITH 00074)
- Humira Pen Psor-Uveits-Adol HS (PREFERRED NDCS STARTING WITH 00074)
- Humira(CF) (PREFERRED NDCS STARTING WITH 00074) subcutaneous syringe kit 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL
- Humira(CF) Pedi Crohns Starter (PREFERRED NDCS STARTING WITH 00074) subcutaneous syringe kit 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL
- Humira(CF) Pen (PREFERRED NDCS STARTING WITH 00074) subcutaneous pen injector kit 40 mg/0.4 mL, 80 mg/0.8 mL
- Humira(CF) Pen Crohns-UC-HS (PREFERRED NDCS STARTING WITH 00074)
- Humira(CF) Pen Pediatric UC (PREFERRED NDCS STARTING WITH 00074)
- Humira(CF) Pen Psor-Uv-Adol HS (PREFERRED NDCS STARTING WITH 00074)

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 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

PA Criteria	Criteria Details
Coverage Duration	Approve through 12/31/24.
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, 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

PA Criteria	Criteria Details
Part B Prerequisite	No

HYFTOR

Products Affected

- Hyftor

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	6 years and older (Initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or a physician who specializes in the management of patients with tuberous sclerosis complex (initial and continuation)
Coverage Duration	Initial-3 months, continuation-1 year
Other Criteria	Facial angiofibroma associated with tuberous sclerosis, initial- approve if the patient meets the following criteria (i. and ii.): i. Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (a or b): a) There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, OR b) According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features (Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque, angiomyolipomas (two or more), cardiac rhabdomyoma, hypomelanotic macules (three or more, at least 5 mm in diameter), lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell astrocytoma, subependymal nodule (two or more), or ungula fibromas (two or more). Minor feature criteria involve confetti skin lesions, dental enamel pits (three or more), intraoral fibromas (two or more), multiple renal cysts, nonrenal hamartomas, retinal achromic patch,

PA Criteria	Criteria Details
	and sclerotic bone lesions), AND ii. Patient has three or more facial angiofibromas that are at least 2 mm in diameter with redness in each. Continuation-approve if the patient meets the following criteria (i. and ii.): i. Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (a or b): a) There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, OR b) According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features (Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque, angiomyolipomas (two or more), cardiac rhabdomyoma, hypomelanotic macules (three or more, at least 5 mm in diameter), lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell astrocytoma, subependymal nodule (two or more), or ungula fibromas (two or more). Minor feature criteria involve confetti skin lesions, dental enamel pits (three or more), intraoral fibromas (two or more), multiple renal cysts, nonrenal hamartomas, retinal achromic patch, and sclerotic bone lesions), AND ii. Patient has responded to Hyftor as evidenced by a reduction in the size and/or redness of the facial angiofibromas.
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	1 year
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. In addition, patients new to therapy must have a trial of Kisqali, Kisqali Femara Co-Pack or

PA Criteria	Criteria Details
	Verzenio prior to approval of Ibrance. 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
Part B Prerequisite	No

ICATIBANT

Products Affected

- Firazyr
- 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

PA Criteria	Criteria Details
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 1 year.
Other Criteria	Patients new to therapy with Acute lymphoblastic leukemia, Philadelphia chromosome positive or chronic myeloid leukemia-approve if the patient has tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel. 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 1 year.
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/Still's-3mos init,1 yr cont.FMF/HIDS/MKD/TRAPS-4mos init,1 yr cont. Acute gout flare-6mos
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

PA Criteria	Criteria Details
	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 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

ILUMYA

Products Affected

- Ilumya

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Approve through 12/31/24.
Other Criteria	Initial Therapy - Approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Skyrizi, Stelara SC, Otezla, or Taltz. A trial of Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm counts as ONE preferred product. 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

IMATINIB

Products Affected

- Gleevec oral tablet 100 mg, 400 mg
- 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	1 year
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. For all diagnoses-generic must be tried before brand. Approve brand Gleevec if the patient has tried generic imatinib mesylate tablets AND the Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the

PA Criteria	Criteria Details
	bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction.
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, GVHD, chronic.
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	GVHD-1 year and older, other-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	CLL- Approve. GVHD-Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, Jakafi [ruxolitinib tablets]). Mantle Cell Lymphoma - approve if the patient has tried one systemic regimen or is not a candidate for a systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, cytarabine, carboplatin, cisplatin, oxaliplatin, or lenalidomide) or if Imbruvica is being used in combination with rituximab prior to induction therapy (e.g., rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) or if Imbruvica is being used as induction or maintenance therapy in combination with chemotherapy. Marginal Zone Lymphoma - approve if the patient has tried at least one systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, or lenalidomide). B-cell lymphoma-approve if the patient has tried at least one systemic regimen (e.g., cisplatin, cytarabine, rituximab, oxaliplatin, gemcitabine, ifosfamide, carboplatin, etoposide, or rituximab).

PA Criteria	Criteria Details
	Central nervous system Lymphoma (primary)- approve if the patient is not a candidate for or is intolerant to high-dose methotrexate OR has tried at least one therapy (e.g., methotrexate, rituximab, vincristine, procarbazine, cytarabine, thiotepa, carmustine, intrathecal methotrexate, cytarabine, or rituximab). Hairy Cell Leukemia - approve if the patient has tried at least two systemic regimens (cladribine, Nipent [pentostatin injection], rituximab, or Pegasys [peginterferon alfa-2a subcutaneous injection]).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma, Marginal Zone Lymphoma, Mantle Cell Lymphoma
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, Esophageal/Esophagogastric Junction Ca, Gastric Ca-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 unresectable or metastatic disease or the patient is not a surgical candidate, Imjudo will be used as first-line systemic therapy in combination with Imfinzi. Non-Small Cell Lung Cancer-Approve if the patient meets ALL of the following criteria (A, B, and C): A) Patient has recurrent, advanced, or metastatic disease, AND B) Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion), AND C) Patient meets ONE of the following (i, ii, iii, or iv): i. Patient meets BOTH of the following (a and b): a) The tumor is negative for actionable molecular markers-Note: Examples of actionable molecular markers include epidermal growth factor receptor (EGFR) mutations, anaplastic lymphoma kinase (ALK) genomic tumor aberrations, KRAS, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), AND b) Imjudo is used as first-line therapy, OR ii. Patient meets both of the following (a and b): a) The tumor is positive for ONE of the following [(1), (2), or (3)]: (1) Epidermal growth factor receptor (EGFR) exon 20 mutation positive, OR (2) KRAS G12C mutation positive, OR (3) ERBB2 (HER2) mutation positive, AND b) Imjudo is used as first-line therapy, OR

PA Criteria	Criteria Details
	iii. Patient meets BOTH of the following (a and b): a) The tumor is positive for ONE of the following [(1), (2), (3), or (4)]: (1) BRAF V600E mutation positive, OR (2) NTRK1/2/3 gene fusion positive, OR (3) MET exon 14 skipping mutation positive, OR (4) RET rearrangement positive, AND b) Imjudo is used as first-line or subsequent therapy, OR iv. Patient meets ALL of the following (a, b, and c): a) The tumor is positive for ONE of the following [(1), (2), (3), or (4)]: (1) EGFR exon 19 deletion or exon 21 L858R mutation positive, OR (2) EGFR S768I, L861Q, and/or G719X mutation positive, OR (3) ALK rearrangement positive, OR (4) ROS1 rearrangement, AND b) The patient has received targeted drug therapy for the specific mutation-Note: Examples of targeted drug therapy include Gilotrif (afatinib tablets), Tagrisso (osimertinib tablets), erlotinib, Iressa (gefitinib tablets), Xalkori (crizotinib capsules), Zykadia (ceritinib capsules), Alecensa (alectinib capsules), Alunbrig (brigatinib tablets), Lorbrena (lorlatinib tablets), Rozlytrek (entrectinib capsules), or Vizimpro (dacomitinib tablets), AND c) Imjudo is used as subsequent therapy. Esophageal and Esophagogastric Junction Cancers, Gastric Cancer-approve if pt has locoregional disease AND has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease AND Imjudo is used as neoadjuvant therapy AND Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion) AND patient is medically fit for surgery.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Esophageal and Esophagogastric Junction Cancers, Gastric Cancer
Part B Prerequisite	No

IMPAVIDO

Products Affected

- Impavido

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 infectious diseases specialist
Coverage Duration	1 month
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INBRIJA

Products Affected

- Inbrija inhalation capsule, w/inhalation device

PA Criteria	Criteria Details
Exclusion Criteria	Asthma, COPD, other chronic underlying lung disease
Required Medical Information	Diagnosis, medications that will be used in combination
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Approve if the patient is currently taking carbidopa-levodopa, is experiencing off episodes and has previously tried one other treatment for off episodes and experienced intolerance or inadequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INFLECTRA

Products Affected

- Inflectra

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medication, medications previously tried
Age Restrictions	CD/UC - Pts aged 6 years or more (initial therapy). PP - Pts aged 18 years or more (initial therapy)
Prescriber Restrictions	Prescr/consult w-RA/AS/SD/JIA/JRA-rheum (initial therapy), PP/Pyoderma gangrenosum/HS-derm (initial therapy), PsA-rheuma/derm (initial therapy), CD/UC-gastro (initial therapy), UV ophthalmologist (initial therapy), GVHD-physician affiliated with a transplant center, onc/heme (initial therapy), Behcet's Disease- rheum, derm, ophthalmologist, gastroenterologist, or neurologist (initial therapy), Sarcoidosis-pulmonol, ophthalmol, or dermatol, cardio or neuro (initial therapy)
Coverage Duration	FDAind init-3mo,cont1yr,GVHD init-1mo,cont-3mo,Pyo Gang-init4 mo,cont1yr,other-init3mo,cont-12 mo
Other Criteria	RA init, patient has tried 1 conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of 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 pt has tried one other aconventional 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,

PA Criteria	Criteria Details
	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 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. Prev trial of one biologic other than requested drug or biosimilar of the requested drug also counts.UV.Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab. Prev trial of one biologic other than requested drug or biosimilar of the requested drug also counts.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

PA Criteria	Criteria Details
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

- Aveed
- Depo-Testosterone
- Testopel
- testosterone cypionate
- testosterone enanthate
- Xyosted

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

PA Criteria	Criteria Details
	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 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 1 year.
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, 400 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	1 year
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	1 year
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

ISTURISA

Products Affected

- Isturisa oral tablet 1 mg, 5 mg

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 disease/syndrome
Coverage Duration	Cushing's-Initial-4 mo, Cont-1 yr. Pt awaiting surgery or response after radiotherapy-4 mo
Other Criteria	Cushing's Disease-Approve if the patient is not a candidate for surgery or surgery has not been curative.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IVERMECTIN (ORAL)

Products Affected

- ivermectin oral
- Stromectol

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

- Asceniv
- Bivigam
- Flebogamma DIF
- Gammagard Liquid
- Gammagard S-D (IgA < 1 mcg/mL)
- Gammaked
- Gammaplex
- Gammaplex (with sorbitol)
- Gamunex-C
- Octagam
- Panzyga
- 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

IWILFIN

Products Affected

- Iwilfin

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	Neuroblastoma-Approve if the patient meets the following (A, B and C): A) Patient has high-risk disease, AND B) The medication is being used to reduce the risk of relapse, AND C) Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy. Note: Examples of anti-GD2 immunotherapy includes Unituxin (dinutuximab intravenous infusion).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IZERVAY

Products Affected

- Izervay

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	Geographic atrophy-approve if the patient has geographic atrophy secondary to age-related macular degeneration and the patient has a best corrected visual acuity (BCVA) in the affected eye of between 20/25 and 20/320 letters.
Indications	All FDA-approved 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	1 year
Other Criteria	For polycythemia vera patients must have tried hydroxyurea or peginterferon alfa-2a. 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 (for example: prednisone, ibrutinib capsules/tablets). 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 2 (JAK2) mutation. 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.

PA Criteria	Criteria Details
Off-Label Uses	Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms
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,

PA Criteria	Criteria Details
	or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules). Richter's Transformation to DLBCL- pt has tried at least one chemotherapy regimen or is not a candidate for a chemotherapy regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Richter's Transformation to Diffuse Large B-Cell Lymphoma
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	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Endometrial cancer-approve if the patient has recurrent, advanced or metastatic disease. 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.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Small Bowel Adenocarcinoma, Colon, Rectal or Appendiceal Cancer
Part B Prerequisite	No

JOENJA

Products Affected

- Joenja

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, pulmonologist, gastroenterologist, hematologist, or an infectious diseases physician who treats patients with primary immune deficiencies (initial)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	Activated phosphoinositide 3-kinase delta syndrome (APDS), initial therapy-approve if the patient meets all of the following criteria (i, ii, and iii): i. Patient weighs greater than or equal to 45 kg, AND ii. Patient has a genetic phosphoinositide 3-kinase delta mutation with a variant in PIK3CD and/or PIK3R1 genes, AND iii. Patient has at least one clinical finding or manifestation consistent with APDS. Note: Examples of clinical findings or manifestations of APDS include recurrent sinopulmonary infections, recurrent herpesvirus infections, lymphadenopathy, hepatomegaly, splenomegaly, nodular lymphoid hyperplasia, autoimmunity, cytopenias, enteropathy, bronchiectasis, and organ dysfunction. Activated phosphoinositide 3-kinase delta syndrome (APDS), continuation-approve if the patient meets all of the following criteria (i, ii, iii, and iv): i. Patient has been established on therapy for at least 6 months, Note: A patient who has received less than 6 months of therapy or who is restarting therapy should be considered under initial therapy.ii. Patient weighs greater than or equal to 45 kg, AND iii. Patient has a genetic phosphoinositide 3-kinase delta mutation with a variant in PIK3CD and/or PIK3R1 genes, AND iv. Patient

PA Criteria	Criteria Details
	has had a positive clinical response in the signs and manifestations of APDS.Note: Examples of positive clinical response in the signs and manifestations of APDS include reduction of: lymph node size, spleen size, immunoglobulin replacement therapy use, infection rate, or immunoglobulin M (IgM) levels.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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

PA Criteria	Criteria Details
	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 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

JYNARQUE

Products Affected

- Jynarque

PA Criteria	Criteria Details
Exclusion Criteria	Patient is currently receiving Samsca (tolvaptan tablets) . Patients with Stage 5 CKD
Required Medical Information	Diagnosis, renal function
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	1 year (initial and continuation)
Other Criteria	Approve if the patient has rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]),according to the prescriber.
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

KALBITOR

Products Affected

- Kalbitor

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 allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders (initial and continuation)
Coverage Duration	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 - approve if patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b): a) Patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values [documentation required] AND b) Patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required]. Patient who has treated previous acute HAE attacks with Kalbitor-approve if the patient has a diagnosis of HAE type I or II [documentation required] AND ii. According to the prescriber, the patient has had a favorable clinical response with Kalbitor treatment.'
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KALYDECO

Products Affected

- Kalydeco

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 and 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 and ARB therapy.

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

KESIMPTA

Products Affected

- Kesimpta Pen

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	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
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

KEVEYIS

Products Affected

- dichlorphenamide
- Keveyis

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of condition, prior medications tried and results, potassium levels
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial 2 months, cont 12 months.
Other Criteria	HypoPP and Related Variants initial must meet all - 1. HypoPP has been confirmed by one of the following - serum potassium concentration of less than 3.5 mEq/L during a paralytic attack, family history of the condition, or a genetically confirmed skeletal muscle calcium or sodium channel mutation, 2. had improvements in paralysis attack symptoms with potassium intake, and 3. tried oral acetazolamide therapy, and 4. according to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient, and 5. the prescribing physician has excluded other reasons for acquired hypokalemia (e.g., renal, adrenal, thyroid dysfunction, renal tubular acidosis, diuretic and laxative abuse). HyperPP and Related Variants initial must meet all - 1. HyperPP has been confirmed by one of the following - an increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack, serum potassium concentration during a paralytic attack of greater than 5.0 mEq/L, a family history of the condition, or genetically confirmed skeletal muscle sodium channel mutation, 2. prescribing physician has excluded other reasons for acquired hyperkalemia (e.g., drug abuse, renal and adrenal dysfunction), 3. tried oral

PA Criteria	Criteria Details
	acetazolamide therapy, 4. according to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient. Cont tx HypoPP and HyperPP - patient has responded to Keveyis (e.g., decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KEVZARA

Products Affected

- Kevzara

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist (initial therapy).
Coverage Duration	Approve through 12/31/24.
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, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Orencia (IV/SC), Rinvoq or Xeljanz/XR (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Cimzia, an infliximab product, golimumab SC/IV, Actemra, or another non-preferred adalimumab product. A trial of multiple adalimumab products counts as ONE preferred product.). OR , B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx - pt must have had a response as determined by the prescriber. Polymyalgia rheumatica, initial-approve if the patient has tried one systemic corticosteroid. Cont tx-pt must have had a response to 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

KINERET

Products Affected

- Kineret

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	N/A
Prescriber Restrictions	Initial therapy only-RA, SJIA and Still's disease, prescribed by or in consultation with a rheumatologist. CAPS (Neonatal-Onset Multisystem Inflammatory Disease or Chronic Infantile Neurological Cutaneous and Articular [CINCA] syndrome), prescribed by or in consultation with a pediatrician, rheumatologist, geneticist, or dermatologist. DIRA-rheum, geneticist, dermatologist, or physician specializing in the treatment of autoinflammatory disorder.
Coverage Duration	Approve through 12/31/24.
Other Criteria	RA initial. Approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Orencia (IV/SC), Rinvoq or Xeljanz/XR. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Actemra, Cimzia, infliximab, Kevzara, golimumab IV/SC or another non-preferred adalimumab product.] A trial of multiple adalimumab products counts as ONE preferred product. DIRA initial-approve if genetic testing has confirmed a mutation in the IL1RN gene. Still's Disease, approve if patient has tried a corticosteroid or has had an inadequate response to 1 conventional synthetic DMARD (eg, methotrexate) for at least 2 months or was intolerant to this therapy OR The patient has at least moderate to

PA Criteria	Criteria Details
	severe active systemic features of this condition, according to the prescriber or the patient has active systemic features with concerns of progression to macrophage activation syndrome as determined by the prescriber. SJIA-initial-approve if the patient has tried one other systemic agent or the patient has at least moderate to severe active systemic features of this condition or the patient has active systemic features with an active joint count of one joint or greater or the patient has active systemic features with concerns of progression to macrophage activation syndrome (MAS). cont tx - approve if the patient had responded to therapy as determined by the prescriber.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Still's disease (SD). Systemic Juvenile Idiopathic Arthritis (SJIA)
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	1 year
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

PA Criteria	Criteria Details
	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, Some Medically-accepted Indications.
Off-Label Uses	Pre/peri-menopausal women with breast cancer in combination with fulvestrant.
Part B Prerequisite	No

KORLYM

Products Affected

- Korlym
- mifepristone oral tablet 300 mg

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. Pt 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

KOSELUGO

Products Affected

- Koselugo

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	Neurofibromatosis Type 1-approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas and if the patient is 2 to 18 years old OR if the patient is 19 years or older if the patient started on therapy with Koselugo prior to becoming 19. Circumscribed Glioma-approve if the patient has recurrent, refractory or progressive disease AND the tumor is BRAF fusion positive OR BRAF V600E activating mutation positive OR patient has neurofibromatosis type 1 mutated glioma AND this medication will be used as a single agent AND the patient is 3-21 years of age OR is greater 21 and has been previously started on therapy with Koselugo prior to becoming 21 years of age. Langerhans Cell Histiocytosis- approve if the patient meets the following criteria (A and B): A) Patient meets one of the following (i, ii, iii, or iv): i. Patient meets both of the following (a and b): a) Patient has multisystem Langerhans cell histiocytosis, AND b) Patient has symptomatic disease or impending organ dysfunction, OR ii. Patient has single system lung Langerhans cell histiocytosis, OR iii. Patient meets all of the following (a, b, and c): a) Patient has single system bone disease, AND b) Patient has not responded to treatment with a bisphosphonate, AND c) Patient has more than 2 bone

PA Criteria	Criteria Details
	lesions, OR iv. Patient has central nervous system disease, AND B) The medication is used as a single agent.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Circumscribed Glioma, Langerhans Cell Histiocytosis
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. Colon or Rectal Cancer-approve if pt has unresectable, advanced, or metastatic disease AND pt has KRAS G12C mutation-positive disease AND medication is prescribed as part of a combination regimen or the patient is unable to tolerate combination therapy AND pt has has previously received a chemotherapy regimen for colon or rectal cancer.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Colon or Rectal cancer
Part B Prerequisite	No

KRYSTEXXA

Products Affected

- Krystexxa

PA Criteria	Criteria Details
Exclusion Criteria	Known Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or a nephrologist
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	Initial therapy for chronic gout - patient must meet all of the following: 1) at least one tophus or history of 2 previous flares in the past year prior to current flare, 2) inadequate response, defined as serum uric acid level that remained greater than 6 mg/dL, following a 3-month trial of a xanthine oxidase inhibitor or contraindication or intolerance to allopurinol, 3) inadequate response, defined as serum uric acid level that remained greater than 6 mg/dL, following a 3-month trial of a uricosuric agent or patient has renal insufficiency, 4) Krystexxa will be used in combination with methotrexate OR methotrexate is contraindicated or not clinically appropriate, 5) Krystexxa will not be used with another uric acid lowering drug. Continuation therapy for chronic gout - patient must meet all of the following: 1) patient is continuing therapy with Krystexxa to maintain response/remission, 2) patient has responded to therapy with evidence of serum uric acid level less than 6 mg/dL with continued Krystexxa treatments, 3) Krystexxa will be used in combination with methotrexate OR methotrexate is contraindicated or not clinically appropriate 4) Krystexxa will not be used with another uric acid lowering drug.

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

LACRISERT

Products Affected

- Lacrisert

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

LAMZEDE

Products Affected

- Lamzede

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 geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.
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. Alpha-mannosidosis-approve if the patient has a confirmed diagnosis of alpha-mannosidosis, defined as alpha-mannosidase activity less than 10 percent of normal activity in blood leukocytes, AND patient has biallelic pathogenic variants in Mannosidase Alpha Class 2B Member 1 (MAN2B1) as confirmed by mutation testing, AND patient has non-central nervous system manifestations. Note: Examples of non-central nervous system manifestations include progressive motor function disturbances, physical disability, hearing and speech impairment, skeletal abnormalities, and immune deficiency.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LANREOTIDE

Products Affected

- lanreotide
- 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 (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). In addition, patients requesting lanretodie, are required to try Somatuline Depot prior to approval. 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 if requesting Somatuline Depot. Patients requesting lanreotide are required to try Somatuline Depot prior to approval. Carcinoid Syndrome-approve Somatuline Depot only.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pheochromocytoma/paraganglioma (Somatuline Depot only)
Part B Prerequisite	No

LAPATINIB

Products Affected

- lapatinib
- Tykerb

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	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
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.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone cancer-chordoma, colon or rectal cancer, breast cancer in pre/peri-menopausal women and men
Part B Prerequisite	No

LEDIPASVIR/SOFOSBUVIR

Products Affected

- ledipasvir-sofosbuvir

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	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1, 4, 5 and 6 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of ledipasvir-sofosbuvir, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No

LEMTRADA

Products Affected

- Lemtrada

PA Criteria	Criteria Details
Exclusion Criteria	Current Use of Lemtrada with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS). Patients with HIV infection.
Required Medical Information	Diagnosis, Previous medication use
Age Restrictions	MS - 17 years of age and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS (initial and continuation)
Coverage Duration	MS, has not completed 1 course of Lemtrada-5 doses. MS, has completed prior course Lemtrada-3 doses
Other Criteria	MS pts who have not completed a course of Lemtrada tx (including pt who started but not completed Lemtrada tx) - patient has a relapsing form of MS, patient must have had an inadequate response or was unable to tolerate according to the prescribing physician TWO disease modifying agents used for MS or the patient has previously received one of Kesimpta, Tysabri, Tyruko, Briumvi, Mavenclad, Lemtrada or Ocrevus or according to the prescribing physician the patient has a highly-active or aggressive multiple sclerosis by meeting one of the following-the patient has demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination OR disabling relapse(s) with suboptimal response to systemic corticosteroids OR magnetic resonance imaging (MRI) findings suggest highly-active or agressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium lesions) OR manifestation of multiple sclerosis-related cognitive impairment. MS patients who already completed a prior course of Lemtrada tx - Approve if the patient has a relapsing form of MS, patient had beneficial clinical response and at least 12 months has

PA Criteria	Criteria Details
	elapsed from the last dose of any prior Lemtrada treatment course for relapsing MS.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LENALIDOMIDE

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 1 year.
Other Criteria	Follicular lymphoma-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one prior therapy. MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide 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

PA Criteria	Criteria Details
	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-approve if the patient has tried at least three other regimens. 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 is used in combination with dexamethasone.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	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.
Part B Prerequisite	No

LENVIMA

Products Affected

- Lenvima oral capsule 10 mg/day (10 mg x 1), 12 mg/day (4 mg x 3), 14 mg/day(10 mg x 1-4 mg x 1), 18 mg/day (10 mg x 1-4 mg x2), 20 mg/day (10 mg x 2), 24 mg/day(10 mg x 2-4 mg x 1), 4 mg, 8 mg/day (4 mg x 2)

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	1 year
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. HCC-approve if the patient has unresectable or metastatic disease. Thymic carcinoma-approve if the patient has tried at least one chemotherapy

PA Criteria	Criteria Details
	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.
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

LEQEMBI

Products Affected

- Leqembi

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	Approve if the patient has a clinical diagnosis of mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease, AND presence of amyloid beta pathology consistent with Alzheimer's disease has been confirmed, AND the patient is receiving the medication as part of either (i or ii): i) a prospective comparative study and the study is CMS-approved, or ii) a clinical trial and the trial is supported by the National Institutes of Health (NIH).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LEQVIO

Products Affected

- Leqvio

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Repatha or Praluent
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medical history
Age Restrictions	18 years 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	N/A
Other Criteria	HeFH approve if pt meets (i, ii or iii): i. Pt has an untreated LDL-C level greater than or equal to 190 mg/dL (prior to treatment with antihyperlipidemic agents), OR ii. Pt has genetic confirmation of heterozygous familial hypercholesterolemia 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 iii. Pt has been diagnosed with heterozygous familial hypercholesterolemia meeting 1 of the following thresholds (a or b): a. Pt meets both of the following: Prescriber used the Dutch Lipid Network criteria to diagnose heterozygous familial hypercholesterolemia AND Patient had a score greater than 5, OR b. Pt meets both of the following: Prescriber used the Simon Broome criteria to diagnose heterozygous familial hypercholesterolemia, AND Pt met the threshold for definite or possible (or probable) familial hypercholesterolemia, AND Pt tried 1 high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) [as a single entity or as a combination product] AND pt has tried 1 high-intensity statin along with

PA Criteria	Criteria Details
	ezetimibe (as a single-entity or as a combination product) for greater than or equal to 8 continuous weeks and LDL-C remains greater than or equal to 70 mg/dL unless the pt experienced 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 d/c of each respective statin therapy. Primary HLD (not assoc with ASCVD or HeFH)- approve if all of the following are met: 1) CAC score 300 Agatston units or higher, AND 2) tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above). ASCVD-approve if pt meets all of the following: Pt has 1 of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, CAD, PAD, undergone a coronary or other arterial revascularization procedure, AND Pt tried 1 high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) [as a single entity or as a combination product] AND pt has tried 1 high-intensity statin along with ezetimibe (as a single-entity or as a combination product) for greater than or equal to 8 continuous weeks and LDL-C remains greater than or equal to 70 mg/dL unless the pt experienced 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 d/c of each respective statin therapy. For all covered diagnoses, pts are required to try Repatha prior to approval of Leqvio.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	N/A
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 that recommends administration in combination with a granulocyte-macrophage colony stimulating factor (examples: dinutuximab or naxitamab).
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. CSCC-approve if the patient meets one of the following (i or ii): (i): pt has has locally advanced, recurrent, or metastatic disease and is not a candidate for curative surgery or curative radiation or (ii): pt has very-high risk, locally advanced, unresectable, or regional disease and this medication will be used as neoadjuvant therapy. Basal Cell Carcinoma-approve if the patient has locally advanced, nodal or metastatic disease. NSCLC-approve if the patient has recurrent, advanced, or metastatic disease. Cervical cancer-approve if pt has local or regional recurrence or distant metastic disease AND this medication is used as subsequent therapy. Vulvar cancer-approve if pt has advanced, recurrent, or metastatic disease AND this medication is used as subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Cervical cancer, vulvar cancer

PA Criteria	Criteria Details
Part B Prerequisite	No

LIDOCAINE PATCH

Products Affected

- DermacinRx Lidocan
- lidocaine topical adhesive patch,medicated 5 %
- Lidocan III
- Lidoderm
- ZTlido

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

LIQREV

Products Affected

- Liqrev

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	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. Patients new to therapy must have tried generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets unless the patient cannot swallow or has difficulty swallowing. Patients currently taking Liqrev are required to have a trial of generic sildenafil 20 mg tablets unless the patient cannot swallow or has difficulty swallowing generic sildenafil 20 mg tablets.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LITFULO

Products Affected

- Litfulo

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with an oral or topical Janus Kinase Inhibitor (JAKi), a biologic immunomodulator or other potent immunosuppressants (e.g., cyclosporine, azathioprine)
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	Alopecia areata, initial therapy: approve if the patient has a current episode of alopecia areata lasting for greater than or equal to 6 months and the patient has greater than or equal to 50 percent scalp hair loss. Alopecia areata, continuation of therapy: approve if the patient has been established on Litfulo for at least 6 months (less than 6 months or a restart, review under initial therapy), and the patient experienced a beneficial clinical response defined as improvement from baseline (prior to initiating Litfulo) in extent and density of scalp hair loss, and the patient continues to require systemic therapy for treatment of alopecia areata.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LIVMARLI

Products Affected

- Livmarli

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	3 months and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or a physician who specializes in Alagille syndrome (initial and continuation)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	Alagille Syndrome, initial-approve if the patient meets (i, ii and iii): i. Patient has moderate-to-severe pruritus, according to prescriber AND ii. Diagnosis of Alagille syndrome was confirmed by genetic testing demonstrating a JAG1 or NOTCH2 deletion or mutation AND iii. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory. Alagille Syndrome, continuation-approve if the patient has had a response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LIVTENCITY

Products Affected

- Livtencity

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with ganciclovir or valganciclovir
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center.
Coverage Duration	2 months
Other Criteria	Cytomegalovirus Infection, Treatment-approve if the patient meets the following criteria (A, B, and C): A) Patient weighs greater than or equal to 35 kg, AND B) Patient is post-transplant, AND Note: This includes patients who are post hematopoietic stem cell transplant or solid organ transplant. C) Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir or patient has a significant intolerance to ganciclovir or valganciclovir.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LODOCO

Products Affected

- Lodoco

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	Atherosclerotic Disease- approve if the patient meets ALL of the following criteria (A, B, C and D): (A) the pt has had one of the following: previous myocardial infarction or a history of an acute coronary syndrome, angina (stable or unstable), past history of stroke or transient ischemic attack, coronary artery disease, peripheral arterial disease, or the patient has undergone a coronary or other arterial revascularization procedure in the past, (B) Lodoco is being added onto other background regimens of other atherosclerotic disease medications [ex: aspirin, antiplatelet agents, anticoagulants, lipid-lowering agents, beta blockers, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers], (C) pt does not have severe hepatic impairment, (D) pt has a creatinine clearance greater than or equal to 15 mL/min.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LONG ACTING OPIOIDS

Products Affected

- Belbuca
- buprenorphine transdermal patch
- Butrans
- ConZip
- hydrocodone bitartrate, oral only, er 12hr
- hydrocodone bitartrate, oral only,ext.rel.24 hr
- hydromorphone oral tablet extended release 24 hr
- Hysingla ER
- 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 capsule, ER multiphase 24 hr
- morphine oral capsule,extend.release pellets 10 mg, 100 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg
- morphine oral tablet extended release
- MS Contin
- Nucynta ER
- oxycodone oral tablet,oral only,ext.rel.12 hr 10 mg, 20 mg, 40 mg, 80 mg
- OxyContin oral tablet,oral only,ext.rel.12 hr 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg
- oxymorphone oral tablet extended release 12 hr
- tramadol oral capsule,ER biphase 24 hr 17-83
- tramadol oral capsule,ER biphase 24 hr 25-75 100 mg, 200 mg
- tramadol oral tablet extended release 24 hr
- tramadol oral tablet, ER multiphase 24 hr
- Xtampza ER

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.

PA Criteria	Criteria Details
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.
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 1 year.
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

LOQTORZI

Products Affected

- Loqtorzi

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.Nasopharyngeal carcinoma- approve if the patient has recurrent, unresectable, oligometastatic, or metastatic disease AND the patient meets ONE of the following (i or ii): i. Patient meets BOTH of the following (a and b): a) Loqtorzi is used for first-line treatment AND b) Loqtorzi is used in combination with cisplatin and gemcitabine, OR ii. Patient meets both of the following (a and b): a) Loqtorzi is used for subsequent treatment AND b) Loqtorzi is used as a single agent.
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	1 year
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 advanced or metastatic NSCLC, as detected by an approved test. In addition, patients new to therapy must also have a trial of Alecensa prior to approval of Lorbrena. NSCLC-ROS1 Rearrangement-Positive, advanced or 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

LUCEMYRA

Products Affected

- Lucemyra

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 14 days
Other Criteria	Opioid withdrawal symptoms-patient is using requested medication to facilitate abrupt opioid discontinuation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LUCENTIS

Products Affected

- Lucentis intravitreal syringe

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

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 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 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

LUMRYZ

Products Affected

- Lumryz

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of sodium oxybate, Xywav, Wakix, Sunosi
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by a sleep specialist physician or a neurologist
Coverage Duration	1 year
Other Criteria	For Excessive daytime sleepiness (EDS) in patients with narcolepsy - 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). 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

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

LUPKYNIS

Products Affected

- Lupkynis

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologics or with cyclophosphamide
Required Medical Information	Diagnosis, lab results (as specified in the Other Criteria field)
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or rheumatologist (initial and continuation)
Coverage Duration	Initial therapy-6 months, continuation-1 year
Other Criteria	Lupus Nephritis, Initial therapy- Approve if the patient meets all of the following criteria (A, B, and C): A) the medication is being used concurrently with an immunosuppressive regimen B) Patient has an estimated glomerular filtration rate (eGFR) greater than 45 mL/min/m2 C) the diagnosis of lupus nephritis has been confirmed on biopsy. Note: For example, World Health Organization class III, IV, or V lupus nephritis. Lupus Nephritis, Continuation therapy- Approve if the medication is being used concurrently with an immunosuppressive regimen and the patient has responded to therapy with the requested medication.
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	1 year
Other Criteria	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

PA Criteria	Criteria Details
	cancer, recurrent or 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

MAVENCLAD

Products Affected

- Mavenclad (10 tablet pack)
- Mavenclad (4 tablet pack)
- Mavenclad (5 tablet pack)
- Mavenclad (6 tablet pack)
- Mavenclad (7 tablet pack)
- Mavenclad (8 tablet pack)
- Mavenclad (9 tablet pack)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis
Required Medical Information	Diagnosis, other medications that will be used in combination
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
Coverage Duration	1 year
Other Criteria	Initial treatment-approve if the patient has tried one preferred S1P drug (Gilenya or Zeposia) AND one preferred fumarate product (generic dimethyl fumarate or Vumerity) prior to approval of Mavenclad. Note: Regarding fumarate products-Prior treatment with brand Tecfidera or Bafiertam, also counts as a fumarate product. A patient who has tried a glatiramer product (Copaxone, Glatopa, generic) does not have to try a fumarate product. Regarding S1P products prior use of a Non-Preferred S1P (i.e., Ponvory, Mayzent) also counts as a trial of a S1P. Patient with underlying cardiovascular disease or risk (for example, patients with heart failure, myocardial infarction, stroke, transient ischemic attack, unstable angina, cardiac arrhythmias, atrioventricular block, bradyarrhythmias) are not required to try an S1P agent. Cont tx-approve if the patient has been established on Mavenclad.
Indications	All FDA-approved Indications.

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

MAVYRET

Products Affected

- Mavyret oral pellets in packet
- Mavyret oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
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	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1, 4, 5 or 6 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of Mavyret, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype 2 and 3 must have an Epclusa or Vosevi trial prior to approval of Mavyret, unless Epclusa and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype unknown/undetermined must have an Epclusa trial prior to approval of Mavyret unless Epclusa is not specifically listed as an alternative therapy for a specific patient population in the guidelines.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No

MAYZENT

Products Affected

- Mayzent oral tablet 0.25 mg, 1 mg, 2 mg
- Mayzent Starter(for 1mg maint)
- Mayzent Starter(for 2mg maint)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
Coverage Duration	1 year
Other Criteria	Initial treatment-Active secondary progressive MS - approve. Patients new to therapy who do not have active secondary progressive MS, approve if the patient has tried one preferred S1P drug (Gilenya or Zeposia) AND one preferred fumarate product (generic dimethyl fumarate or Vumerity). Regarding fumarate products, Prior use of brand Tecfidera or Bafiertam with inadequate efficacy or significant intolerance (according to the prescriber) also counts as a fumarate product. A patient who has tried a glatiramer product (Copaxone, Glatopa, generic) does not have to try a fumarate product. Regarding S1P products-prior use of a Non-Preferred S1P (i.e., Ponvory) also counts.Cont tx-approve if the patient has been established on Mayzent or if the patient has active secondary progressive MS.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MEGESTROL

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	1 year and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
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 or the patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafinlar. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation postive 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 (a, b, or c): a) Pilocytic astrocytoma OR b)

PA Criteria	Criteria Details
	Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma 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 following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR patient has Erdheim Chester disease or Rosai-Dorfman 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	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	Authorization will be for 1 year.
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
- memantine oral tablets,dose pack
- Namenda Titration Pak
- Namenda XR oral capsule,sprinkle,ER 24hr
- 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

MIGLUSTAT

Products Affected

- miglustat
- Yargesa
- Zavesca

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 geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of Gaucher disease or related disorders
Coverage Duration	1 year
Other Criteria	Gaucher Disease Type 1-approve if the diagnosis is established by one of the following (i or ii): i. Demonstration of deficient Beta-glucocerebrosidase activity in leukocytes or fibroblasts, OR ii. Molecular genetic testing documenting glucocerebrosidase gene mutation.
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
- Nuvigil
- Provigil 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 the patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults-if the patient is concurrently receiving other medication therapy for depression. 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	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 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, Some Medically-accepted Indications.
Off-Label Uses	B-Cell Lymphoma
Part B Prerequisite	No

MULPLETA

Products Affected

- Mulpleta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, platelet count, date of procedure
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	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 8 to 14 days after starting Mulpleta therapy.
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

MYCAPSSA

Products Affected

- Mycapssa

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 endocrinologist
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 if the patient has tried Somatuline depot prior to approval of Mycapssa.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MYFEMBREE

Products Affected

- Myfembree

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	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	24 months of total therapy between Myfembree or Oriahnn
Other Criteria	Uterine Fibroids (Leiomyomas)-approve if the patient is premenopausal (before menopause) and is experiencing heavy menstrual bleeding associated with the uterine fibroids, the uterine fibroids have been confirmed by a pelvic ultrasound, including transvaginal ultrasonography or sonohysterography, hysteroscopy, or magnetic resonance imaging. Endometriosis-approve if the patient is premenopausal and patient has previously tried one of the following (i or ii): i. A contraceptive (e.g., combination oral contraceptives, levnorgestrel-releasing intrauterine systems, a depo-medroxyprogesterone injection), unless contraindicated OR ii. An oral progesterone (e.g., norethindrone tablets), unless contraindicated.Note: An exception to this requirement can be made if the patient has previously used a gonadotropin-releasing hormone agonist (e.g., Lupron Depot [leuprolide depot suspenion]) or Orilissa (elagolix tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

MYOBLOC

Products Affected

- Myobloc

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic uses
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Hyperhidrosis, Palmar or Primary Axillary-approve if the patient has tried Botox. Upper Limb Spasticity - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Hyperhidrosis, Palmar or primary axillary, Upper Limb Spasticity
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 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	1 year
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

NEULASTA

Products Affected

- Neulasta
- Neulasta Onpro

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

PA Criteria	Criteria Details
	prior to approval of Neulasta unless patient has a diagnosis of radiation syndrome.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No

NEUPOGEN

Products Affected

- Neupogen

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. SCN - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. Radiation-prescribed by or in consult with an oncologist, radiologist, or radiation oncologist
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 months.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT- 3 mo. Radiation-1 mo.
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 or renal dysfunction, poor performance status, HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine,

PA Criteria	Criteria Details
	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 [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection). Patients are required to try Zarxio and Nivestym prior to approval of Neupogen unless patient has initiated therapy with Neupogen and requires additional medication to complete the current cycle of chemotherapy.
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. Acute lymphocytic leukemia (ALL).
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

PA Criteria	Criteria Details
	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, CAD, 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

PA Criteria	Criteria Details
	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, CAD, 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 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

NEXVIAZYME

Products Affected

- Nexviazyme

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 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	Acid alpha-glucosidase deficiency (Pompe Disease)-approve if the patient has late-onset acid alpha-glucosidase deficiency (late-onset Pompe Disease) and the diagnosis is established by laboratory test demonstrating deficient acid alpha-glucosidase activity in the 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

NGENLA

Products Affected

- Ngenla

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results (e.g., growth hormone stim test results, growth rates, pituitary hormone levels, MRI/CT results)
Age Restrictions	Greater than or equal to 3 years of age and less than 18 years old
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist (all dx except hypophysectomy)
Coverage Duration	1 year
Other Criteria	GHD ped pts, initial-Approve if A and B: A) Pt has tried Omnitrope w inadequate efficacy or significant intolerance (If not tried Omnitrope, a trial of Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ, Saizen, or Zomacton with inadequate efficacy or significant intolerance counts) AND B)Pt meets one of (i, ii, iii, iv, or v): i.Pt meets one of (1 or 2): (1)Pt had two GH stim tests with any of: L-dopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND both show peak GH response below the normal ref range for the testing lab OR (2)Pt meets BOTH of (a and b): (a)Pt had one GH stim test with any of: L-dopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND shows a peak GH response below normal ref range for the testing lab AND (b)Pt has at least one risk factor for GH def (ex: ht for age curve deviated down across two major ht percentiles [e.g., above 25th to below 10th percentile], growth rate less than expected normal growth rate for age and gender, low IGF-1 and/or IGFBP-3 levels, very low peak GH level on provocative testing as defined by the prescribing physician, growth velocity less than 10th percentile for age and gender [height velocity percentile is NOT the same as height-for-age percentile], pt is a/p craniopharyngioma resection, pt has

PA Criteria	Criteria Details
	optic nerve hypoplasia, pt has a GH gene deletion) ii.Pt has undergone brain radiation or tumor resection AND pt meets at least one of (1 or 2): (1)Pt had one GH stim test with any of: L-dopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND test shows a peak GH response below normal ref range for the testing lab OR (2)Pt has a deficiency in at least one other pituitary hormone (i.e., ACTH, TSH, gonadotropin [LH and/or FSH deficiency counted as one], or prolactin) iii.Pt has congenital hypopituitarism AND meets one of (1, 2 or 3): (1) Pt had one GH stim test with any of: L-dopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows a peak GH response below normal ref range as determined by testing lab OR (2) Pt has a deficiency in at least one other pituitary hormone (i.e., ACTH, TSH, gonadotropin [LH and/or FSH deficiency counted as one], or prolactin) OR (3)Pt has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk iv. Pt has multiple pituitary hormone deficiencies and meets one of (1 or 2): (1)Pt has three or more pituitary hormone deficiencies: somatropin (GH), ACTH, TSH, gonadotropin (LH and/or FSH deficiency counted as one), and prolactin, OR (2)Pt has had one GH stim test with any of: L-dopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows a peak GH response below normal ref range as determined by the testing lab v. Pt has had a hypophysectomy (surgical removal of pituitary gland)-approve. GHD in pediatric pts, continuation-approve if the pt is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NILUTAMIDE

Products Affected

- Nilandron
- nilutamide

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	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 1 year.
Other Criteria	MM - be used in combination with lenalidomide or cyclophosphamide 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	No

NITISINONE

Products Affected

- nitisinone
- Nityr
- Orfadin

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of 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, 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,ALL,BMT-3mo.Radiation-1 mo, 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

PA Criteria	Criteria Details
	frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).
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.Acute lymphocytic leukemia (ALL), Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome)
Part B Prerequisite	No

NOCDURNA

Products Affected

- Nocdurna (men)
- Nocdurna (women)

PA Criteria	Criteria Details
Exclusion Criteria	Currently receiving loop diuretics, systemic or inhaled glucocorticoids OR renal impairment with an estimated glomerular filtration rate less than 50 mL/min/1.73 per meter squared OR heart failure OR polydipsia OR known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion
Required Medical Information	Diagnosis, lab values
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a urologist, a geriatrician, nephrologist or an endocrinologist
Coverage Duration	12 months
Other Criteria	Prior to desmopressin therapy, the patient awakens at least two times per night to void AND the patient has serum sodium concentrations within the normal range (135 to 145 mmol/L) AND the diagnosis of nocturnal polyuria has been confirmed with a 24-hour urine collection before treatment initiation and the patient meets one of the following (i or ii): i. The nocturnal urine volume exceeds 20% of the total 24-hour urine volume in patients less than 65 years of age OR ii. The nocturnal urine volume exceeds 33% of the total 24-hour urine volume in patients greater than or equal to 65 years of age.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NON-INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- Androderm
- AndroGel transdermal gel in metered-dose pump
- AndroGel transdermal gel in packet 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)
- Fortesta
- Jatenzo oral capsule 158 mg, 198 mg, 237 mg
- Natesto
- Testim
- 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
- Tlando
- Vogelxo

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

PA Criteria	Criteria Details
	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 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

NOURIANZ

Products Affected

- Nourianz

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	3 years
Other Criteria	Parkinson's disease, patients with off episodes-approve if the patient is experiencing off episodes and if the patient is currently taking carbidopa-levodopa.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NPLATE

Products Affected

- Nplate

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Thrombocytopenia, Chemotherapy-Induced: 18 years of age and older
Prescriber Restrictions	ITP- prescribed by or in consultation with a hematologist (initial therapy only). Thrombocytopenia, Chemotherapy-Induced /MDS (initial therapy only)- prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	HemSyndofAcuteRadi Synd-1mo. ITP/MDSinit3 mo.cont 1 yr.Thrombo Chemo-Induced - init 3 mo, cont 6 mo
Other Criteria	Hematopoietic Syndrome of Acute Radiation Syndrome - approve if the patient has been acutely exposed to myelosuppressive doses of radiation. ITP - initial- platelet count less than 30,000 per microL or less than 50,000 per microL and the patient is at an increased risk of bleeding AND patient has tried at least one other therapy or has undergone splenectomy. Continuation - pt demonstrates a beneficial clinical response and remains at risk for bleeding complications. Thrombocytopenia, Chemotherapy-Induced - initial - platelet count less than 100,000 per microL AND patient has thrombocytopenia at least 3 weeks after the most recent dose of chemotherapy or has experienced a delay in chemotherapy administration related to thrombocytopenia. Continuation - pt continues to receive treatment with chemotherapy and demonstrates a beneficial response to Nplate. Thrombocytopenia in MDS - initial - pt has low- to intermediate-risk MDS AND has platelet count less than 30,000 per microL or less than 50,000 per microL and the patient is at an increased risk of bleeding. Continuation - pt demonstrates a beneficial clinical response and remains at risk for bleeding complications.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Thrombocytopenia, Chemotherapy-Induced and Thrombocytopenia in Myelodysplastic Syndrome
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	1 year
Other Criteria	Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) agonist 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 another monoclonal antibody therapy.
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 initial, 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 Nucala or another monoclonal antibody therapy that may lower blood eosinophil levels) AND has received combo tx w/inhaled corticosteroid AND at least 1 additional asthma controller/maintenance med (Examples: LAMA, LABA, leukotriene receptor antagonist, monoclonal antibody) AND pt's asthma cont to be uncontrolled, or was uncontrolled prior to starting Nucala or another monoclonal antibody therapy for asthma 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, urgent care visit or ED visit in the prev yr, pt has a FEV1 less than 80 percent predicted, Pt has FEV1/FVC less than

PA Criteria	Criteria Details
	0.80, or Pt's asthma worsens upon taper of oral (systemic) corticosteroid therapy. 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 cells per microliter within the previous 6 wks or within 6 wks prior to any monoclonal antibody that may lower blood eosinophil levels. 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 monoclonal antibody that may lower blood eosinophil levels, 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

NULIBRY

Products Affected

- Nulibry

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 pediatrician, geneticist, or a physician who specializes in molybdenum cofactor deficiency (MoCD) Type A
Coverage Duration	Authorization will be 1 year
Other Criteria	Molybdenum Cofactor Deficiency (MoCD) Type A-approve if the patient has genetic testing confirmation of a mutation in the MOCS1 gene
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	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention if Nurtec ODT is being taking for the preventive treatment of episodic migraine.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine, Acute treatment-approve if the patient has tried at least one triptan or has a contraindication to triptans. 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 experienced adverse events severe enough to warrant discontinuation. 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. In addition, if the patient is currently taking Nurtec ODT, the patient has had a significant clinical benefit from the medication.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
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.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
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 therapy)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial therapy)
Coverage Duration	6 months initial, 1 year continuation.
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)). Patients new to therapy and continuing therapy must not have cirrhosis or must have compensated cirrhosis without evidence of portal hypertension.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
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 Briumvi or Kesimpta prior to approval of Ocrevus. (Note: Prior treatment with Lemtrada, Tysabri, Tyruko (natalizimab-sztn intravenous infusion), Mavenclad, Ocrevus or Kesimpta can bypass the Briumvi requirement). 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
- Sandostatin injection solution 100 mcg/mL, 50 mcg/mL, 500 mcg/mL

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

ODACTRA

Products Affected

- Odactra

PA Criteria	Criteria Details
Exclusion Criteria	The patient is NOT currently receiving SC or SL allergen immunotherapy
Required Medical Information	Diagnosis
Age Restrictions	Greater than or equal to 12 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	House Dust Mite (HDM)-Induced Allergic Rhinitis (AR)-approve if the diagnosis is confirmed by meeting ONE of the following conditions (i or ii): i. The patient has a positive skin test response to house dust mite allergen extracts OR ii. The patient has a positive in vitro test (i.e., a blood test for allergen-specific IgE antibodies) for house dust mite (HDM).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	1 year
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, if the disease is limited to nodal metastases. (Note-This includes primary or recurrent nodal metastases. A patient with distant metastasis does not meet this requirement).
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

PA Criteria	Criteria Details
Part B Prerequisite	No

OGSIVEO

Products Affected

- Ogsiveo

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	Desmoid tumors (aggressive fibromatosis)-approve if the patient has progressing desmoid tumors, the desmoid tumors are not amenable to surgery or radiotherapy and if the patient requires systemic treatment. Note: Progressing desmoid tumors are defined as greater than or equal to 20 percent progression within 12 months
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 (a or b): a) the patient has anemia, defined as hemoglobin less than 10g/dL or b) the patient has platelet count greater than or equal to 50x109/L.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OLPRUVA

Products Affected

- Olpruva

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant therapy with another phenylbutyrate product
Required Medical Information	Diagnosis
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 diagnosed with genetic test, 3 months diagnosed with hyperammonemia lab test
Other Criteria	Urea cycle disorder (e.g., deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase)-approve if the diagnosis was confirmed by genetic testing confirming a mutation resulting in a urea cycle disorder or if the patient has hyperammonemia diagnosed with an ammonia level above the upper limit of the normal reference range for the reporting laboratory. Patients are required to have a trial of generic sodium phenylbutyrate oral suspension or tablets prior to approval of Olpruva, unless the patient does not have a feeding tube.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OLUMIANT

Products Affected

- Olumiant

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics, DMARDs, or other potent immunosuppressants. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).
Required Medical Information	Diagnosis, previous medication use, concurrent medication
Age Restrictions	Alopecia areata-18 years and older (initial/cont).All other dx-18 years of age and older (initial therapy)
Prescriber Restrictions	RA-Prescribed by or in consultation with a rheumatologist (initial therapy). Alopecia Areata-prescribed by or in consultation with a dermatologist (initial/cont).
Coverage Duration	Approve through 12/31/24.
Other Criteria	Initial therapy, RA - approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Orencia (IV/SC), Rinvoq or Xeljanz/XR. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Actemra IV/SC, Cimzia, infliximab, Simponi golimumab IV/SC, Kevzara, or a non-preferred adalimumab product. A trial of multiple adalimumab product counts as ONE preferred product.] Continuation therapy - approve if the patient has had a response, as determined by the prescriber. Alopecia areata-approve if the patient has a current episode of alopecia areata lasting for greater than or equal to 6 months and has greater than or equal to 50 percent scalp hair loss. Continuation-approve if the patient has experienced an improvement from baseline in extent and density of scalp hair loss and

PA Criteria	Criteria Details
	if the prescriber states the patient continues to require systemic therapy for the treatment of alopecia areata.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OMVOH IV

Products Affected

- Omvoh

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD).
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	3 doses for induction
Other Criteria	Ulcerative colitis-Approve if the patient meets the following (A and B): A) The medication will be used as induction therapy, AND B) the patient has had a trial of TWO of the following: Stelara, Entyvio IV, Remicade, or an adalimumab product [i.e., Humira, Cyltezo, adalimumab adbm, Hyrimoz (NDCs starting with 61314), adalimumab-adaz]. Trial(s) of Zymfentra or a Non-Preferred IV infliximab product, Simponi SC, Entyvio SC, or a Non-Preferred adalimumab product will also count.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OMVOH SC

Products Affected

- Omvoh Pen

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD).
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	1 year
Other Criteria	Ulcerative colitis, initial - Approve if the patient meets i and ii: i. Patient will receive three induction doses with Omvoh intravenous within 3 months of initiating therapy with Omvoh subcutaneous, AND ii.the patient has had a trial of TWO of the following: Stelara, Entyvio IV, Remicade, or an adalimumab product [i.e., Humira, Cyltezo, adalimumab adbm, Hyrimoz (NDCs starting with 61314), adalimumab-adaz]. Trial(s) of Zymfentra or a Non-Preferred IV infliximab product, Simponi SC, Entyvio SC, or a Non-Preferred adalimumab product will also count. Ulcerative colitis, continuation-approve if the patient has had a response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ONGENTYS

Products Affected

- Ongentys

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	Parkinson's Disease-Approve if the patient is currently receiving carbidopa/levodopa therapy or if the patient is currently receiving Ongentys.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ONPATTRO

Products Affected

- Onpattro

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Tegsedi or a tafamidis product
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Approve if the patient has a documented transthyretin (TTR) mutation verified by genetic testing and the patient has symptomatic polyneuropathy (e.g., reduced motor strength/coordination, impaired sensation [e.g., pain, temperature, vibration, touch]).
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	1 year
Other Criteria	AML - Approve if the medication is used for post-remission maintenance therapy AND the patient has intermediate or poor-risk cytogenetics OR has complete response to previous intensive induction chemotherapy AND the patient has declined or is not fit or eligible for allogeneic hematopoietic stem cell transplant.
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, biliary tract cancers, soft tissue sarcoma
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

OPFOLDA

Products Affected

- Opfolda

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 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	Acid alpha-glucosidase deficiency (Pompe Disease)- Approve if the patient meets the following (A, B, C and D): A)Patient weighs greater than or equal to 40 kg, AND B) The medication will be used in combination with Pombiliti, AND C)Patient has not demonstrated an improvement in objective measures after receiving one of the following for at least one year (i or ii): Note: Examples of objective measures include forced vital capacity (FVC) and six-minute walk test (6MWT) i. Lumizyme (alglucosidase alfa) intravenous infusion, OR ii. Nexviazyme (avalglucosidase alfa-ngpt) intravenous infusion, AND D)Patient has late-onset acid alpha-glucosidase deficiency (late-onset Pompe disease) with diagnosis established by one of the following (i or ii): i.Patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue, OR ii.Patient has a molecular genetic test demonstrating acid alpha-glucosidase gene mutation.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
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
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 1 year.
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

OPZELURA

Products Affected

- Opzelura

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with other JAK inhibitors.Concurrent use with other potent immunosuppressants
Required Medical Information	Diagnosis, other medications tried
Age Restrictions	12 years and older
Prescriber Restrictions	AD-Prescribed by or in consultation with an allergist, immunologist or dermatologist. Vitiligo-prescribed by or in consultation with a dermatologist.
Coverage Duration	AD-8 weeks, vitiligo-6 months
Other Criteria	Atopic Dermatitis, mild to moderate- Approve if the patient meets all of the following (A, B, C and D): A) Patient has mild to moderate atopic dermatitis, according to the prescriber, AND B) Patient has atopic dermatitis involvement estimated to affect less than or equal to 20 percent of the body surface area, AND C) Patient meets ONE of the following (i or ii): i. Patient meets ALL of the following criteria (a and b): a) Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid AND Note: Concomitant use of a topical corticosteroid in with a topical calcineurin inhibitor would meet the requirement. AND b) Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber, OR ii. Patient is treating atopic dermatitis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia AND D) Patients meets ALL of the following (i and ii): i. Patient has tried at least one topical calcineurin inhibitor, AND Note: Examples of topical calcineurin inhibitors include tacrolimus ointment (Protopic, generic) and pimecrolimus cream (Elidel, generic). Concomitant use of a topical calcineurin inhibitor with a topical

PA Criteria	Criteria Details
	corticosteroid would meet the requirement. ii. Inadequate efficacy was demonstrated with this topical calcineurin inhibitor, according to the prescriber. Vitiligo-approve if the patient meets all of the following (A, B, and C): A) patient has nonsegmental vitiligo, AND B) Patient has vitiligo involvement estimated to affect less than or equal to 10 percent of the body surface area, AND C) Patient meets ONE of the following (i or ii): i. patient has tried at least one high-, and/or super-high-potency prescription topical corticosteroid, AND Inadequate efficacy was demonstrated with this topical corticosteroid therapy OR ii. Patient is treating vitiligo affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia.
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	Approve through 12/31/24.
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

ORENITRAM

Products Affected

- Orenitram
- Orenitram Month 1 Titration Kt
- Orenitram Month 2 Titration Kt
- Orenitram Month 3 Titration Kt

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.
Required Medical Information	Diagnosis, results of right heart cath
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	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). For initial Orenitram therapy, approve Orenitram if the patient has tried Uptravi or if the patient is receiving a strong cytochrome P450 2C8 inhibitor (e.g., gemfibrozil).
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

ORIAHNN

Products Affected

- Oriahnn

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results
Age Restrictions	18 years and older
Prescriber Restrictions	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	24 months of total therapy
Other Criteria	Heavy menstrual bleeding associated with uterine fibroids-approve if the patient is premenopausal and uterine fibroids have been confirmed by a pelvic ultrasound, hysteroscopy or magnetic resonance imaging.
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	1 year
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

OSMOLEX

Products Affected

- Osmolex ER oral tablet, IR - ER, biphasic 24hr 129 mg, 193 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Previous medications tried, concurrent medications
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial and continuation).
Coverage Duration	Initial-3 months. Cont-1 year.
Other Criteria	Initial therapy - approve if the following criteria are met: patient has tried immediate-release amantadine capsules, tablets, or oral solution and derived benefit but had intolerable adverse events as determined by the prescriber OR the patient could not achieve a high enough dosage to gain adequate benefit as determined by the prescriber. Continuation therapy - approve if the following criteria are met: patient has tried immediate-release amantadine capsules, tablets, or oral solution and derived benefit but had intolerable adverse events as determined by the prescriber OR the patient could not achieve a high enough dosage to gain adequate benefit as determined by the prescriber AND the patient has had a response to therapy as determined by the prescriber.
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)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD).
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	Approve through 12/31/24.
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

PA Criteria	Criteria Details
Part B Prerequisite	No

OXBRYTA

Products Affected

- Oxbryta oral tablet 300 mg, 500 mg
- Oxbryta oral tablet for suspension

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	4 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (initial and continuation)
Coverage Duration	1 year
Other Criteria	Sickle Cell Disease Initial-approve if the patient has had at least one sickle cell-related crisis in the previous 12-month period (only applies to patients 12 years and older), AND baseline hemoglobin level was less than or equal to 10.5 g/dL (before initiating Oxbryta therapy) AND patient meets one of the following criteria (a, b, or c): a. Patient is currently receiving a hydroxyurea product OR b. patient has tried a hydroxyurea product and has experienced inadequate efficacy or significant intolerance OR c. patient is not a candidate for hydroxyurea therapy. Cont-approve if the patient is receiving clinical benefit from Oxbryta therapy.
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

OXLUMO

Products Affected

- Oxlumo

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 nephrologist or urologist (initial therapy)
Coverage Duration	Initial-6 months, Cont-1 year
Other Criteria	Primary Hyperoxaluria Type 1 Initial therapy-Approve if the patient meets i, ii, and iii: i. Patient has had a genetic test confirming the diagnosis of Primary Hyperoxaluria Type 1 via identification of an alanine:glyoxylate aminotransferase gene (AGXT) mutation AND ii. Patient has ONE of the following (a, b or c): a) Patient has a urinary oxalate excretion greather than or equal to 0.7 mmol/24 hours/1.73 meters2 OR b) Patient has a urinary oxalate:creatinine ratio above the age-specific upper limit of normal or c. patient has a plasma oxalate level greater than or equal to 20 micromol/L AND iii. Patient has not previously received a liver transplant for primary hyperoxaluria Type 1. Primary Hyperoxaluria Type 1 Continuation therapy-approve if the patient is continuing to derive benefit from Oxlumo as determined by the most recent (i.e., within the past 6 months) objective measurement. Note: Examples of objective measurements of a response to Oxlumo therapy are reduced urinary oxalate excretion, decreased urinary oxalate:creatinine ratio, or reduced plasma oxalate levels from baseline (i.e., prior to Oxlumo therapy) or improved or stabilized clinical signs/symptoms of Primary Hyperoxaluria Type 1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment).

PA Criteria	Criteria Details
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 meets either (i or ii): (i): Padcev is used as first-line therapy and will be used in combination with Keytruda (pembrolizumab intravenous infusion), or (ii): Padcev is used as subsequent therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PALFORZIA

Products Affected

- Palforzia (Level 1)
- Palforzia (Level 2)
- Palforzia (Level 3)
- Palforzia (Level 4)
- Palforzia (Level 5)
- Palforzia (Level 6)
- Palforzia (Level 7)
- Palforzia (Level 8)
- Palforzia (Level 9)
- Palforzia (Level 10)
- Palforzia (Level 11 Up-Dose)
- Palforzia Initial Dose
- Palforzia Level 11 Maintenance

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results
Age Restrictions	Patients between the ages of 4 and 17. Patients 18 and older must have started therapy prior to turning 18.
Prescriber Restrictions	Prescribed by or in consultation with an allergist or immunologist
Coverage Duration	1 year
Other Criteria	Peanut allergy-approve if the patient meets A, B AND C: A) Patient has a positive skin prick test (SPT) response to peanut with a wheal diameter greater than or equal to 3 mm larger than the negative control, AND B) Patient has a positive in vitro test for peanut specific IgE with a level greater than or equal to 0.35 kUA/L, AND C) Palforzia will be used in conjunction with a peanut-avoidant diet.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PALYNZIQ

Products Affected

- Palynziq subcutaneous syringe 10 mg/0.5 mL, 2.5 mg/0.5 mL, 20 mg/mL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, phenylalanine concentrations
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	1 year (initial and continuation)
Other Criteria	Initial therapy - approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., prior treatment with Kuvan). Maintenance therapy - approve if the patient has experienced improvement while on Palynziq.
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 1 year.
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

- Cuprimine
- Depen Titratabs
- penicillamine

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	Cystinuria-if brand name is requested, approve if the patient has tried generic penicillamine and cannot take generic penicillamine due to a formulation difference in the inactive ingredients between the brand and the bioequivalent generic product which would result in a significant allergy or serious adverse reaction. Wilson's disease-approve if diagnosis 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, d): a) Presence of Kayser-Fleischer rings, b) Serum ceruloplasmin level less than 20 mg/dL, c) Liver biopsy findings consistent with Wilson's disease, d) 24-hour urinary copper greater than 40 mcg/24 hours AND if brand name is requested, approve if the patient has tried generic penicillamine and cannot take generic penicillamine due to a formulation difference in the inactive ingredients between the brand and the bioequivalent generic product which would result in a significant allergy or serious adverse reaction.
Indications	All FDA-approved Indications.

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

PHENYLBUTYRATE

Products Affected

- Buphenyl
- Pheburane
- Ravicti
- sodium phenylbutyrate

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant therapy with more than one phenylbutyrate product
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 diagnosed with an ammonia level 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

PHEOCHROMOCYTOMA

Products Affected

- Demser
- Dibenzyline
- metyrosine
- phenoxybenzamine

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 therapy for phenoxybenzamine, initial and continuation therapy for metyrosine)
Coverage Duration	Authorization will be for 1 year
Other Criteria	If brand Dibenzyline is being requested, approve if the patient has tried and cannot take generic phenoxybenzamine due to a formulation difference in the inactive ingredients between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction. If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin) AND the patient has tried phenoxybenzamine (brand or generic). If the requested drug is 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

PHESGO

Products Affected

- Phesgo

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	Neoadjuvant or adjuvant-1 year (total), metastatic disease-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-Neoadjuvant or Adjuvant Therapy-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease and the patient meets one of the following criteria (i or ii): i. The medication will be used in combination with chemotherapy OR ii. Phesgo is continued after chemotherapy to complete 1 year of neoadjuvant or adjuvant therapy. Breast Cancer-Metastatic Disease-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease AND the patient has not been previously treated with anti-HER2 therapy or chemotherapy for metastatic disease AND the medication will be used in combination with chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use With Guanylate Cyclase Stimulators.
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 and suspension (Revatio, generics) 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	1 year
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, male or pre/perimenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist 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 or fulvestrant) 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

PIRFENIDONE

Products Affected

- Esbriet oral capsule
- Esbriet oral tablet 267 mg, 801 mg
- pirfenidone oral capsule
- pirfenidone oral tablet 267 mg, 801 mg
- pirfenidone oral tablet 534 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. For patients requesting Esbriet capsules (267 mg), Esbriet tablets (267 mg and 801 mg), or branded generic pirfenidone 534 mg tablets, patients must have a trial of generic pirfenidone tablets (267 mg and 801 mg) or generic pirfenidone capsules (267 mg).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PLIAGLIS

Products Affected

- Pliaglis

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic uses
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 week
Other Criteria	Superficial dermatological procedures-approve for non-cosmetic conditions if the medication will be applied to intact skin.
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/High-Grade B-Cell Lymphoma-Approve if the patient has International Prognostic Index score of greater than or equal to 2 and will use Polivy as first line therapy OR the patient has been treated with at least one prior chemotherapy regimen. B-Cell Lymphoma (Examples include follicular lymphoma, AIDS-related B-cell lymphoma, post-transplant lymphoproliferative disorders, histologic transformation of indolent lymphomas to diffuse large 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 1 year.
Other Criteria	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). CNS Lymphoma-approve if the patient has relapsed or refractory disease. 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

POMBILITI

Products Affected

- Pombiliti

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 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	Acid alpha-glucosidase deficiency (Pompe Disease)- Approve if the patient meets the following (A, B, C and D): A)Patient weighs greater than or equal to 40 kg, AND B)The medication will be used in combination with Opfolda, AND C) Patient has not demonstrated an improvement in objective measures after receiving one of the following for at least one year (i or ii): Note: Examples of objective measures include forced vital capacity (FVC) and six-minute walk test (6MWT). i.Lumizyme (alglucosidase alfa) intravenous infusion, OR ii. Nexviazyme (avalglucosidase alfa-ngpt) intravenous infusion, AND D)Patient has late-onset acid alpha-glucosidase deficiency (late-onset Pompe disease) with diagnosis established by one of the following (i or ii): i. Patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue, OR ii. Patient has a molecular genetic test demonstrating acid alpha-glucosidase gene mutation.
Indications	All FDA-approved Indications.

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

PONVORY

Products Affected

- Ponvory
- Ponvory 14-Day Starter Pack

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
Coverage Duration	1 year
Other Criteria	Patients new to therapy-approve if the patient has tried one preferred fumarate-based product (generic dimethyl fumarate, or Vumerity) AND one Preferred S1P receptor modulator (Gilenya or Zeposia). Note: Prior use of brand Tecfidera or Bafiertam with inadequate efficacy or significant intolerance (according to the prescriber) also counts as a fumarate product. Also, a patient who has prevIously tried a glatiramer product (Copaxone, Glatopa, generic) can bypass the fumarate requirement. Prior use of a Non-Preferred S1P (i.e., Mayzent) also counts. Cont tx-approve if the patient has been established on Ponvory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

POSACONAZOLE (ORAL)

Products Affected

- Noxafil oral susp,delayed release for recon
- Noxafil oral suspension
- Noxafil oral tablet,delayed release (DR/EC)
- posaconazole oral suspension
- 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, esophageal candida-6 mo, all others-3 months
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	esophageal candidiasis - treatment, mucormycosis - 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

PRADAXA

Products Affected

- Pradaxa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior medication history (all as described in Other Criteria field)
Age Restrictions	Capsules-A.fib/flutter/DVT or PE px in pt w/hip replacement surg/DVT px in pt with knee replacement surg-18 years and older, capsules-DVT or PE Tx/DVT or PE, to reduce risk of recurrence-8 years and older, pellets-3 months to less than 12 years
Prescriber Restrictions	N/A
Coverage Duration	A fib/flutter/DVT/PE tx/reduce risk of recurr-1 yr,DVT/PE prophy(hip)/DVT prophy(knee)-60days.
Other Criteria	Approve Pradaxa capsules for Atrial Fibrillation (or Atrial Flutter) if the patient has tried Eliquis or Xarelto. Approve Pradaxa capsules for Deep Vein Thrombosis or Pulmonary Embolism, Treatment-if the patient meets one of the following criteria (A or B): A) The patient has tried Eliquis or Xarelto OR B) The patient is currently receiving Pradaxa for this condition. Approve Pradaxa capsules for Deep Vein Thrombosis or Pulmonary Embolism, to reduce the risk of recurrence if the patient has tried Eliquis or Xarelto. Approve Pradaxa capsules for Deep Vein Thrombosis or Pulmonary Embolism, Prophylaxis Following Hip Replacement Surgery if the patient meets one of the following (A or B): A) The patient has tried Eliquis or Xarelto OR B) The patient is currently receiving Pradaxa for this condition. Approve Pradaxa capsules for Deep Vein Thrombosis in Patients Undergoing Knee Replacement Surgery, Prophylaxis if the patient meets one of the following criteria (A or B): A) The patient has tried Eliquis or Xarelto OR B) The patient is currently receiving Pradaxa for this condition.

PA Criteria	Criteria Details
	Approve Pradaxa Pellets if the patient has a diagnosis of venous thromboembolic events, treatment or venous thromboembolic events, to reduce the risk of recurrence.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Deep Vein Thrombosis in patients undergoing knee replacement surgery, prophylaxis
Part B Prerequisite	No

PRALUENT

Products Affected

- Praluent Pen

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Leqvio or Repatha.
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, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
Coverage Duration	Authorization will be for 1 year
Other Criteria	Hyperlipidemia in patients with HeFH -approve if meets all of the following 1. Pt has been diagnosed with HeFH AND 2. tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND 3. LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during d/c. Hyperlipidemia Pt with Clinical ASCVD-approve if meets all of the following: has one of the following conditions prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, CAD, PAD, undergone a coronary or other arterial revascularization procedure, AND tried ONE high intensity statin (as defined above) AND LDL-C remains greater than or equal to 70 mg/dL unless the pt is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-

PA Criteria	Criteria Details
	related symptoms resolved during d/c. Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if all of the following are met: 1) coronary artery calcium or calcification (CAC) score 300 Agatston units or higher, AND 2) tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above). For all covered diagnoses, patients are required to try Repatha prior to approval of Praluent.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PRETOMANID

Products Affected

- pretomanid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	Patients 18 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 Extensively Drug Resistant or Treatment-Intolerant or Nonresponsive Multidrug-Resistant-approve if prescribed in combination with Sirturo (bedaquiline tablets) and linezolid tablets or oral suspension.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PREVYMIS

Products Affected

- Prevymis intravenous
- Prevymis oral

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

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

PA Criteria	Criteria Details
	orchiectomy. Treatment of bone loss (to increase bone mass) in patients at high risk for fracture receiving adjuvant AI therapy for breast cancer, approve if the patient has breast cancer that is not metastatic to the bone and in receiving concurrent AI therapy (eg, anastrozole, letrozole, exemestane). 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

PA Criteria	Criteria Details
	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 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

- Daraprim
- 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

PYRUKYND

Products Affected

- Pyrukynd oral tablet 20 mg, 5 mg, 5 mg (4-week pack), 50 mg
- Pyrukynd oral tablets,dose pack

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a hematologist (initial and continuation)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	Initial therapy-Approve if the patient has the presence of at least two variant/mutant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene and at least one of the variant/mutant alleles was a missense variant AND the patient has a current hemoglobin level less than or equal to 10g/dL or patient is currently receiving red blood cell transfusions regularly, defined as at least six transfusion within the last year. Continuation of therapy-Approve if the patient has the presence of at least two variant/mutant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene and at least one of the variant/mutant alleles was a missense variant AND the patient has a current hemoglobin level less than or equal to 12 g/dL AND the patient has experienced a benefit from therapy, defined as increase in or maintenance of hemoglobin levels, or improvement in or maintenance of hemolysis laboratory parameters, OR decrease in or maintenance of transfusion requirements.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
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 1 year.
Other Criteria	Gastrointestinal stromal tumor (GIST)-approve if the patient has tried imatinib or avapritinib tablets, AND the patient meets one of the following criteria (i, ii, or iii): i. Patient has tried sunitinib and regorafenib tablets, OR ii. Patient has tried dasatinib tablets, OR iii. Patient is intolerant of sunitinib. 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

QULIPTA

Products Affected

- Qulipta

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Preventive treatment of episodic migraine-approve if the patient meets (A and B): A) Patient has greater than or equal to 4 and less than 15 migraine headache days per month (prior to initiating a migraine-preventative medication B) Patient has tried Nurtec ODT prior to approval of Qulipta. Chronic migraine prevention-approve if the patient has greater than or equal to 15 migraine headache days per month (prior to initiating a migraine-preventative medication).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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. In addition, patients are required to have a trial of Radicava ORS or if patient cannot use Radicava ORS due to its route of administration (e.g., patients who are unable to swallow and not on a feeding tube) or if the patient has already been started on Radicava IV.

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

RADICAVA ORS

Products Affected

- Radicava ORS
- Radicava ORS Starter Kit Susp

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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

RAPID-ACTING INSULIN

Products Affected

- Admelog U-100 Insulin lispro
- Apidra U-100 Insulin
- Fiasp U-100 Insulin
- insulin aspart U-100 subcutaneous solution
- Novolog U-100 Insulin aspart

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	If the patient is requesting an insulin lispro product approve if the patient has tried two of the following: Humalog (any formulation), Lyumjev (any formulation) or Insulin Lispro vial. If the request is for an insulin aspart product, approve if the patient has tried one of the following: Humalog (any formulation), Lyumjev (any formulation) or Insulin Lispro vial. Please note a trial of Admelog or insulin lispro pen would also count. If the request is for an insulin glulisine product, approve if the patient has tried one of the following: Humalog (any formulation), Lyumjev (any formulation) or Insulin Lispro 10 ml vial. Please note a trial of Admelog or insulin lispro pen would also count. If the patient is using an insulin pump that is not compatible with insulin lispro, approve the requested drug.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

REBIF

Products Affected

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

PA Criteria	Criteria Details
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	Initial treatment-approve if the patient has tried TWO of the following: Avonex, Plegridy, Betaseron, or generic glatiramer. Cont tx-approve if the patient has been established on Rebif.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REBLOZYL

Products Affected

- Reblozyl

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Beta-thal-Prescribed by or in consultation with a hematologist (initial therapy), MDS/Myelodysplastic/myeloproliferative neoplasm-prescribed by or in consultation with oncologist or hematologist (initial therapy)
Coverage Duration	Beta thal-Ini-4 mo,cont-1 yr.MDS/myelodysplastic/myeloproliferative neoplasm ini-6 mo, cont-1 yr
Other Criteria	Beta-Thalassemia-initial therapy-approve if according to the prescriber, the patient requires regular red blood cell transfusions (Note: This includes patients who are transfusion-dependent) and the patient has not received Zynteglo in the past. Beta-Thalassemia-continuation-approve if according to the prescriber, the patient has experienced a clinically meaningful decrease in transfusion burden and the patient has not received Zynteglo in the past. MDS-approve if the patient has myelodysplastic syndromes with ring sideroblasts or serum erythropoietin level is less than or equal to 500 mU/mL AND patient has very low- to intermediate-risk myelodysplastic syndromes Note: This is determined using the International Prognostic Scoring System (IPSS) AND patient does not have a confirmed mutation with deletion 5q (del 5q) AND patient currently requires blood transfusions, defined as at least two red blood cell units over the previous 8 weeks AND Pretreatment hemoglobin level is less than 10.0 g/dL AND Reblozyl will not be used in combination with an erythropoiesis stimulating agent.Continuation of Therapy-approve if the patient has experienced a clinically meaningful decrease in transfusion burden.

PA Criteria	Criteria Details
	Myelodysplastic/myeloproliferative neoplasm-approve if the patient has myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis-associated anemia AND patient has very low- to intermediate-risk disease.Note: This is determined using the International Prognostic Scoring System (IPSS) AND patient does not have a confirmed mutation with deletion 5q (del 5q) AND pt currently requires blood transfusions, defined as at least two red blood cell units over the previous 8 weeks AND Pretreatment hemoglobin level is less than 10.0 g/dL AND Reblozyl will not be used in combination with an erythropoiesis stimulating agent.Continuation of Therapy-approve if the patient has experienced a clinically meaningful decrease in transfusion burden.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RECLAST

Products Affected

- Reclast
- 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

PA Criteria	Criteria Details
	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 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

RECORLEV

Products Affected

- Recorlev

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of endogenous Cushing's syndrome.
Coverage Duration	1 year
Other Criteria	Endogenous Cushing's Syndrome-approve if the patient has hypercortisolemia, the patient is not a candidate for surgery or surgery has not been curative and the patient has tried ketoconazole tablets.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RELEUKO

Products Affected

- Releuko subcutaneous

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, SCN-hematologist, HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS, Radiation syndrome-prescribed by or in consultation with expert in acute radiation
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT-3 mo.Radi-1 mo,other-12mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: A) 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 B) 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), OR C) patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis

PA Criteria	Criteria Details
	with a colony stimulating factor (eg, Leukine, filgramstim products, pegfilgrastim products and a reduced dose or frequency of chemotherapy may compromise treatment, OR D) patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection). Patients are required to try Zarxio and Nivestym prior to approval of Releuko unless patient has initiated therapy with Releuko and requires additional medication to complete the current cycle of chemotherapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neutropenia associated with HIV or AIDS, Treatment of myelodysplastic syndromes (MDS), Drug induced agranulocytosis or neutropenia, Acute lymphocytic leukemia (ALL), Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome)
Part B Prerequisite	No

RELYVRIO

Products Affected

- Relyvrio

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
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	6 months
Other Criteria	ALS, initial therapy - Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi): i. The patient has a definite diagnosis of amyotrophic lateral sclerosis (ALS) based on the application of the revised El Escorial criteria, AND ii. Patient does not have a tracheostomy, AND iii. Patient has a percent-predicted slow vital capacity (SVC) greater than 60 percent based on gender, height, and age, AND iv. Onset of ALS symptoms began within the preceding 18 months, AND v. Patient meets one of the following (i, ii, or iii): i. Patient has previously received a riluzole product, OR ii. Patient is currently receiving a riluzole product, OR iii. Patient will take Relyvrio concomitantly with a riluzole product, AND Note: Examples of riluzole products include riluzole tablets, Tiglutik (riluzole oral suspension), or Exservan (riluzole oral film). vi. Patient will not use Relyvrio concomitantly with any other medications containing phenylbutyrate or taurursodiol, including over-the-counter supplements. ALS, continuation therapy - Approve if the patient will not use Relyvrio concomitantly with any other medications containing phenylbutyrate or taurursodiol, including

PA Criteria	Criteria Details
	over-the-counter supplements, AND the patient continues to benefit from therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REMICADE

Products Affected

- infliximab
- 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/JRA-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, cardio/neuro.
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, pt has tried 1 conventional synthetic DMARD for at least 3 months (note: pts who have already had a 3-mo trial of 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 pt has tried 1 other conventional systemic therapy for CD OR pt has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR pt has had ileocolonic resection.Note-previous trial of biologic also counts as a trial of 1 other agent for CD. UC-Tried 1 systemic agent or was intolerant to one of these agents OR the pt has pouchitis AND has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine 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 1 conventional tx (eg,

PA Criteria	Criteria Details
	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 1 conventional therapy can be made if the pt has already had a trial of at least 1 tumor necrosis factor for Behcet's disease. These pts 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.Prev trial of 1 biologic other than requested drug or biosimilar of the requested drug also counts. UV.Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab. Prev trial of 1 biologic other than requested drug or biosimilar of the requested drug also counts.Sarcoidosis.Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG).Tried 1 systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to 1 of these agents. HS.Tried 1 tx (eg, intralesional/oral CS, systemic antibiotic, isotretinoin).GVHD.Tried 1 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 1 biologic DMARD [eg, Humira, Orencia, Enbrel, Kineret, Actemra]) or the pt has aggressive disease. PP- approve if the patient has tried at least 1 traditional systemic agent for psoriasis for at least 3 months, unless intolerant or pt 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. For all covered diagnoses, if the request is for infliximab a trial of Remicade is required prior to approval.
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

- Remodulin
- treprostinil sodium

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Oral or Inhaled Prostacyclin Agents Used for Pulmonary Hypertension.
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

PA Criteria	Criteria Details
	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 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. Patients requesting brand name Remodulin, who are new to therapy or have been taking brand name Remodulin for less than 90 days are required to try generic treprostinil and cannot take generic treprostinil due to a formulation difference in the inactive ingredients (e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction. If the patient is requesting brand name Remodulin subcutaneous continuous infusion and cannot take generic treprostinil because appropriate durable medical equipment is not available such as the patient does not have or cannot obtain a compatible pump that allows generic treprostinil to be administered-Approve the brand subcutaneous product. If the patient is requesting brand name Remodulin and has been stabilized on brand name product for 90 days or more, approve the requested brand name product.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RENFLEXIS

Products Affected

- Renflexis

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medication, medications previously tried
Age Restrictions	CD/UC - Pts aged 6 years or more (initial therapy). PP-Pts aged 18 years and older (initial therapy)
Prescriber Restrictions	Prescr/consult w-RA/AS/SD/JIA-rheum (initial therapy), PP/Pyoderma gangrenosum/HS-derm (initial therapy), PsA-rheum/derm(initial therapy), CD/UC-gastro(initial therapy), UV ophthalmologist (initial therapy), GVHD-physician affiliated with a transplant center, onco/heme(initial therapy), Behcets Disease- rheum, derm, ophthalmologist, gastro, or neurologist (initial therapy), Sarcoidosis-pulmonol, ophthalmol, cardio, neuro or dermatol (initial therapy)
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	Initial therapy-for all covered diagnoses-Approve if the patient has tried Remicade. 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, Still's disease, Uveitis, Pyoderma gangrenosum, Hidradenitis suppurativa, Graft-versus-host disease, Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis
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: 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 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, CAD, 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

PA Criteria	Criteria Details
	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 higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)- approve if all of the following are met: 1) coronary artery calcium or calcification (CAC) score 300 Agatston units or higher, AND 2) tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above).
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 1 year.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has recurrent, advanced or metastatic disease AND the tumor is RET fusion-positive. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion positive or RET mutation positive disease AND the patient meets i or ii: i. patient has anaplastic thyroid cancer OR ii. the disease requires treatment with systemic therapy and patient has medullary thyroid cancer or the disease is radioactive iodine-refractory. Solid tumors-approve if the patient has recurrent, advanced or metastatic disease and the tumor is rearranged during transfection (RET) fusion-positive. Histiocytic neoplasm-approve if the patient has a rearranged during transfection (RET) fusion and has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anaplastic thyroid carcinoma, histiocytic neoplasm

PA Criteria	Criteria Details
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

REYVOW

Products Affected

- Reyvow 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	Approve if the patient has tried Nurtec or Ubrelvy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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

REZUROCK

Products Affected

- Rezurock

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Graft-versus-host disease-approve if the patient has chronic graft-versus-host disease and has tried at least two conventional systemic treatments (e.g., ibrutinib, cyclosporine) for chronic graft-versus-host disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RIABNI

Products Affected

- Riabni

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	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Patients are required to try Ruxience prior to approval of Riabni unless the patient has already been started on or has previously received Riabni.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RILUZOLE

Products Affected

- Exservan
- Rilutek
- riluzole
- Teglutik
- Tiglutik

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 a biologic immunomodulator.
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	Approve through 12/31/24.
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 systemic 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 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

PA Criteria	Criteria Details
	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 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

RITUXAN

Products Affected

- Rituxan
- Rituxan Hycela

PA Criteria	Criteria Details
Exclusion Criteria	Rituximab will not be used concurrently with another biologic or with a targeted synthetic DMARD (RA diagnosis)-initial therapy
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	RA-prescribed by or in consultation with a rheumatologist (initial therapy)
Coverage Duration	RA-1 month, all others-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. RA (initial course), approve if patient has tried one conventional synthetic DMARD for at least 3 months. Note-if the patient has already had a 3-month trial of at least one biologic, these patients are not required to step back and try a conventional synthetic DMARD. Continuation-approve if 16 weeks or more will elapse between treatment courses and if the patient has already received two or more courses of therapy, the patient has responded to therapy as determined by the prescriber. Patients are required to try Ruxience prior to approval of Rituxan unless the patient has already been started on or has previously received Rituxan, if the patient has a diagnosis of RA, Pemphigus vulgaris or if the patient has a diagnosis of granulomatosis with polyangitis and is greater than or equal to 2 years of age but less than 18.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

ROFLUMILAST (ORAL)

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). For patients requesting brand Daliresp, approve if the patient has tried generic roflumilast AND brand Daliresp is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the corresponding generic product which, would result in a significant allergy or serious adverse reaction.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ROLVEDON

Products Affected

- Rolvedon

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 hematologist
Coverage Duration	6 months
Other Criteria	Cancer patients receiving myelosuppressive chemotherapy, approve if the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, OR the patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. Patients are required to try Ziextenzo or Nyvepria prior to approval of Rolvedon.
Indications	All FDA-approved Indications.

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

ROZLYTREK

Products Affected

- Rozlytrek oral capsule 100 mg, 200 mg
- Rozlytrek oral pellets in packet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years and older, Solid Tumors-1 month and older, Pediatric Diffuse High-Grade Glioma-less than 18 years old
Prescriber Restrictions	N/A
Coverage Duration	1 year
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 and the mutation was detected by an approved test. Pediatric Diffuse High-Grade Glioma- approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used either as adjuvant therapy or for recurrent or progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pediatric Diffuse High-Grade Glioma
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	1 year
Other Criteria	Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient is in complete or partial response after a platinum-based chemotherapy regimen and the patient is in complete or partial response to first-line primary treatment or if the patient has recurrent disease and has a BRCA mutation. 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.

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

RUFINAMIDE

Products Affected

- Banzel
- 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	1 year
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/Extranodal NK/T-Cell Lymphoma - approve if the patient has a systemic allergic reaction or anaphylaxis to a pegylated asparaginase product.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Extranodal NK/T-Cell Lymphoma
Part B Prerequisite	No

RYPLAZIM

Products Affected

- Ryplazim

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	Initial-3 months, Continuation-1 year
Other Criteria	Plasminogen Deficiency Type 1 (Hypoplasminogenemia), Initial Therapy-Approve if the patient meets both of the following criteria (A and B): A. Patient has a diagnosis of plasminogen deficiency type 1 confirmed by Biallelic mutations in the PLG gene AND baseline plasminogen activity level (prior to initiating Ryplazim) less than or equal to 45 percent of normal based on the reference range for the reporting laboratory, AND B. Patient has a history of lesions and symptoms consistent with a diagnosis of congenital plasminogen deficiency.Plasminogen Deficiency Type 1 (Hypoplasminogenemia), Continuation of therapy-Approve if the patient meets one the following criteria (A or B): A. Patient has had a clinical response to Ryplazim, as determined by the prescriber (Note: Examples of clinical response include resolution of active lesions, stabilization of current lesions, and prevention of new or recurrent lesions), OR B. Patient has a trough plasminogen activity level greater than or equal to 10 percent (absolute change in plasminogen activity) above the baseline trough level (prior to initiating Ryplazim).
Indications	All FDA-approved Indications.

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

RYSTIGGO

Products Affected

- Rystiggo

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 neurologist
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Generalized Myasthenia Gravis, initial therapy: Approve if the patient meets all of the following (A, B, C, D and E): A) patient has confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis or confirmed anti-muscle-specific tyrosine kinase antibody-positive generalized myasthenia gravis, and B) patient has Myasthenia Gravis Foundation of America class II to IV and Myasthenia Gravis Activities of Daily Living (MG-ADL) total score at least 3 for non-ocular symptoms, and C) Patient received or is currently receiving pyridostigmine or has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine, and D) Patient has evidence of unresolved symptoms of generalized myasthenia gravis, for example: difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility), and E) Treatment cycles are no more frequent than every 63 days from the start of the previous treatment cycle. Generalized Myasthenia Gravis, continuation of therapy: Approve if the patient is continuing to derive benefit from

PA Criteria	Criteria Details
	Rystiggo (for example: reductions in exacerbations of myasthenia gravis, improvements in speech, swallowing, mobility, and respiratory function) and treatment cycles are no more frequent than every 63 days from the start of the previous treatment cycle.
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.

PA Criteria	Criteria Details
Off-Label Uses	Pheochromocytoma/paraganglioma, Meningioma, Thymoma and thymic carcinoma
Part B Prerequisite	No

SAPHNELO

Products Affected

- Saphnelo

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist (initial and continuation)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	Systemic lupus erythematosus, initial-approve if the patient has autoantibody-positive SLE, defined as positive for at least one of the following: antinuclear antibodies (ANA), anti-double-stranded DNA (anti-dsDNA) antibodies, anti-Smith (anti-Sm) antibodies AND if the medication is being used concurrently with at least one other standard therapy (e.g., hydroxychloroquine, prednisone) OR the patient is determined to be intolerant to standard therapy due to a significant toxicity. Systemic lupus erythematosus, continuation-approve if the medication is being used concurrently with at least one other standard therapy (e.g., hydroxychloroquine, prednisone) OR the patient is determined to be intolerant to standard therapy due to a significant toxicity and if the patient has responded to Saphnelo.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

SAPROPTERIN

Products Affected

- Javygtor
- Kuvan
- 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

SAVAYSA

Products Affected

- Savaysa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior medication history (as described in Other Criteria)
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Atrial fib/flutter/DVT/PE treatment-1 year
Other Criteria	Atrial Fibrillation (or Atrial Flutter). Approve if the patient meets both of the following criteria (A and B): A) The patient has an estimated creatinine clearance (CrCl) less than or equal to 95 mL/min AND B) The patient has tried Eliquis or Xarelto. Deep Vein Thrombosis or Pulmonary Embolism, Treatment. Approve if the patient meets one of the following-patient has tried Eliquis or Xarelto OR patient is currently receiving Savaysa for this condition.
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	1 year
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

SIGNIFOR

Products Affected

- Signifor
- Signifor LAR

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

SILIQ

Products Affected

- Siliq

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Previous medication use
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Approve through 12/31/24.
Other Criteria	Initial therapy-Plaque Psoriasis-Approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Skyrizi, Stelara SC, Otezla, or Taltz. A trial of multiple adalimumab products count as ONE Preferred Product. Continuation Therapy - approve if the patient had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SIMPONI

Products Affected

- Simponi subcutaneous pen injector 100 mg/mL, 50 mg/0.5 mL
- Simponi subcutaneous syringe 100 mg/mL, 50 mg/0.5 mL

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	UC-18 years and older (initial therapy)
Prescriber Restrictions	All dx-initial only-RA/Ankylosing spondylitis, prescribed by or in consultation with a rheumatologist. Psoriatic arthritis, prescribed by or in consultation with a rheumatologist or dermatologist. UC-prescribed by or in consultation with a gastroenterologist
Coverage Duration	Approve through 12/31/24.
Other Criteria	AS, initial -approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Xeljanz/XR, Taltz. Note: A previous trial of a nonpreferred adalimumab product would also count. A trial of multiple adalimumab products counts as ONE preferred product. PsA, initial-approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Taltz, Stelara, Otezla, Orencia, Rinvoq, Skyrizi, Xeljanz/XR. Note: A previous trial of a nonpreferred adalimumab product would also count. A trial of multiple adalimumab products counts as ONE preferred product. RA, initial- approve if the patient has tried two of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Orencia, Rinvoq or Xeljanz/XR. Note: A previous trial

PA Criteria	Criteria Details
	of a nonpreferred adalimumab product would also count. A trial of multiple adalimumab products counts as ONE preferred product. Ulcerative colitis, initial - approve if the patient has had a trial with an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm]. Note: A previous trial of a nonpreferred adalimumab product would also count. Continuation tx - approve if the pt had a response as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SIMPONI ARIA

Products Affected

- Simponi ARIA

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	N/A
Prescriber Restrictions	RA, AS/JIA/JRA - Prescribed by or in consultation with a rheumatologist (initial therapy). PsA - Prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy).
Coverage Duration	Approve through 12/31/24.
Other Criteria	RA - Approve if the patient has tried TWO of the following: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Orencia, or Xeljanz/XR. (Note: if the patient has not tried TWO of these drugs listed, a previous trial with Cimzia, infliximab, Actemra, Kevzara, Kineret, a non-preferred adalimumab or Rituxan can count toward meeting the try TWO requirement. A trial of multiple adalimumab products counts as ONE preferred product.) PsA - Approve if the patient has tried TWO of the following: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm]Humira, Taltz, Stelara, Otezla, Orencia, Rinvoq, Skyrizi, Xeljanz/XR. (Note: if the patient has not tried TWO of these drugs listed, a previous trial with Cimzia, Cosentyx, a non-preferred adalimumab or infliximab can count toward meeting the try TWO requirement. A trial of multiple adalimumab products counts as ONE preferred product.) AS-Approve if the patient has tried TWO of the following: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with

PA Criteria	Criteria Details
	61314-), adalimumab-adaz, adalimumab-adbm], Xeljanz/XR, Taltz (Note: if the patient has not tried TWO of these drugs listed, a previous trial with Cimzia, Cosentyx, a non-preferred adalimumab or infliximab can count toward meeting the try TWO requirement. A trial of multiple adalimumab products counts as ONE preferred product.) 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 if the patient has tried one other medication for this condition OR b) Patient has aggressive disease, as determined by the prescriber. Cont tx - must have a response to therapy as according to prescriber.
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

SKYCLARYS

Products Affected

- Skyclarys

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	16 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, or a physician who specializes in ataxias and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	Friedreich's Ataxia, initial therapy-approve if the patient meets ALL of the following (i, ii, iii, and iv): i. Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia, AND ii. Patient has had ALL of the following in the last year (a, b, and c): a) Patient has a B-type natriuretic peptide (BNP) less than or equal to 200 pg/mL, AND b) Patient has a left ventricular ejection fraction greater than or equal to 40 percent, AND c) Patient has a hemoglobin A1c (HbA1c) less than or equal to 11 percent, AND iii. Patient has been assessed using the modified Friedreich's Ataxia Rating Scale and has a score greater than or equal to 20, but less than or equal to 80, AND iv. Patient is ambulatory. Friedreich's Ataxia, continuation-approve if the patient meets ALL of the following (i and ii): i. Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia, AND ii. Patient continues to benefit from therapy, as demonstrated by a slowed progression on the modified Friedreich's Ataxia Rating Scale. Note: Examples of positive clinical response in the signs and manifestations of APDS include reduction of: lymph node size, spleen

PA Criteria	Criteria Details
	size, immunoglobulin replacement therapy use, infection rate, or immunoglobulin M (IgM) levels.
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	PP-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	Approve through 12/31/24.
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

PA Criteria	Criteria Details
	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. 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

SKYTROFA

Products Affected

- Skytrofa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results (e.g., growth hormone stim test results, growth rates, pituitary hormone levels, MRI/CT results)
Age Restrictions	Greater than or equal to 1 year of age and less than 18 years old
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist (all dx except hypophysectomy)
Coverage Duration	1 year
Other Criteria	GHD in pediatric pt, initial-Approve if pt meets A and B:A)Pt tried Omnitrope and experi inadeq efficacy or sig intol (Note:If pt has not tried Omnitrope, trial of Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ, Saizen, or Zomacton with inadeq efficacy or sig intol can count towards meeting this requirement) AND B)Pt meets 1 of the following (i, ii, iii, iv, or v): i.Pt meets 1 of the following (1 or 2): (1)Pt had 2 GH stim tests with following:levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND both tests show an inadeq resp as defined by peak GH resp which is below normal range as determined lab OR (2)Pt meets BOTH of the following (a and b): (a)Pt had at least 1 GH stim test with following:levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND test shows an inadeq resp as defined by peak GH resp which is below normal range as determined by lab AND (b)Pt has at least 1 risk factor for GHD(e.g., ht for age curve has deviated downward across 2 major height percentiles, child's growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels) ii.Pt has undergone brain radi or tumor resection AND pt meets at least 1 of the following (1 or 2): (1)Pt has had 1 GH stim test with

PA Criteria	Criteria Details
	the following:levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND test shows an inadeq resp defined by a peak GH resp which is below normal range as determined by lab OR (2) Pt has def in at least 1 other pituitary hormone (i.e., adrenocorticotropic hormone, TSH, gonadotropin [LH and/or FSH def are counted as 1 def], or prolactin) iii. Pt has congenital hypopituitarism AND meets 1 of following (1 or 2): (1)Pt had 1 GH stim test with following:levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND test shows an inadeq resp defined by peak GH response which is below normal range as determined by lab OR (2)Pt has a def in at least 1 other pit hormone (i.e., adrenocorticotropic hormone, TSH, gonadotropin [LH and/or FSH def are counted as 1 def], or prolactin) and/or the pt has imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk iv. Pt has panhypopituitarism and meets one of the following (1, 2, or 3): (1) Pt has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on MRI or CT, OR (2) Pt has 3 or more of the following pit hormone deficiencies: somatropin, adrenocorticotropic hormone, TSH, gonadotropin (LH and/or FSH def are counted as 1 def), and prolactin, OR (3) Pt has had 1 GH stim test with the following:levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadeq resp defined by a peak GH response which is below normal range as determined by lab. v. Patient has had a hypophysectomy-approve. GHD in a pediatric pt, cont-approve if the pt is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SOFOSBUVIR/VELPATASVIR

Products Affected

- sofosbuvir-velpatasvir

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	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied according to AASLD guidelines. And, patients with genotype 1, 4, 5 and 6 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of sofosbuvir-velpatasvir, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype 2 and 3 must have an Epclusa or Vosevi trial prior to approval of sofosbuvir-velpatasvir, unless Epclusa and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype unknown/undetermined must have an Epclusa trial prior to approval of sofosbuvir-velpatasvir.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No

SOGROYA

Products Affected

- Sogroya

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results (e.g., growth hormone stim test results)
Age Restrictions	Greater than or equal to 2.5 year of age
Prescriber Restrictions	Prescribed by or in consulation with an endocrinologist (all dx except hypophysectomy)
Coverage Duration	1 year
Other Criteria	GHD child/adol,init-1of(i,ii,iii,iv,or,v):i. Either(1or2):1-Two stim tests w/ levodopa,insulin-induced hypoglyc, arginine, clonidine, or glucagon w/ BOTH resp below lab norm OR 2- BOTH (a and b):a-One stim test below lab norm AND b-at least 1 GHD risk factor ii.Brain radiation/tumor resection AND (1or2):1-One stim test below lab norm OR 2-One other pit horm defic (ACTH,TSH,gonadotrop[LH, FSH are 1],prolactin), OR iii.congenital hypopit AND one of (1,2or3):1-one stim test resp below lab norm OR 2-one other pit horm def OR 3-Imaging triad ectopic posterior pit and pit hypoplasia w/ abn pit stalk. iv.Mult pit horm defic and 1 of (1or2):1-3+ pit horm def: somatrop,ACTH,TSH,gonadotrop,prolact, OR 2-one stim test below lab norm. v.Hypophysectomy. GHD child/adol, cont-pt respond to tx. GHD Adult/TransitionAdol-ALL of (A,B,C,andD):A)endo certify not for anti-aging/athletic ability/body building,AND B)GHD that is 1 of:Child onset OR Adult onset from 1 of:GHD alone or mult horm def (hypopit) from pit dz, hypothalam dz, pit surgery, cranial radiation tx, tumor tx, TBI, or subarach hem, AND C)one of (i,ii,or iii): i.Known perinatal insults OR congenital/genetic defects, OR ii.ALL of: 3+ pit horm def: ACTH, TSH, gonadotropin defic, prolactin, AND IGF-1 below lab

PA Criteria	Criteria Details
	norm, AND Other causes of low IGF-1 excluded, OR iii. 1 of (a or b):a-Adult-Neg resp to stim test (1,2,3,4,5,or6):Note: arginine test peak less/eq to 0.4mcg/L, meets neg resp stim test. 1-Insulin tol test (3 GH levels in atleast 60min [not incl time zero], w/adeq hypoglycemia) peak less/equal to 5mcg/L, OR 2-Glucagon stim test (GST) (3 GH levels in atleast 180min[not incl time 0]) peak less/eq to 3mcg/L AND BMI less than 25, OR 3-GST peak less/eq to 3mcg/L AND BMI gr/eq to 25 and less/eq to 30 w/ hi pretest prob of GHD, OR 4-GST peak less/eq to 1mcg/L AND BMI gr/eq to and less/eq to 30 w/low pretest prob of GHD, OR 5-GST peak less/eq to 1mcg/L AND BMI gr than 30, OR 6-Macrilen test (4 GH levels in atleast 90min[not incl time 0]) peak less than 2.8ng/mL AND BMI gr/eq to 40. OR b-Transition adol-BOTH of (1and2): Note: Macrilen peak less than 2.8ng/mL meets neg resp to stim.1-Pt off GH tx for at least month before retest AND 2-one of:(i,ii,iii,iv,v,or,vi): i-Insulin tol test peak less/eq to 5mcg/L, OR ii.GST peak less/eq to 3mcg/L AND BMI less than 25, OR iii. GST peak less/eq to 3mcg/L AND BMI gr/eq to 25 and less/eq to 30 w/hi pretest prob of GHD, OR iv-GST peak less/eq to 1mcg/L AND BMI gr/eq to 25 and less/eq to 30 w/ low pretest prob of GHD, OR v-GST peak less/eq to 1mcg/L AND BMI greater than 30, OR vi-If both insulin tol test AND GST contraind, arginine test can be used (3 GH levels in atleast 120min[not incl time 0]) peak less/eq to 0.4mcg/L. In addition for all dx-pt tried Omnitrope and experienced inadequate efficacy or signif intol (Note: If not tried Omnitrope, trial of Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ, Saizen, or Zomacton w/ inadeq efficacy, signif intol can count).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SOHONOS

Products Affected

- Sohonos oral capsule 1 mg, 1.5 mg, 10 mg, 2.5 mg, 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Female-8 years or older. Male-10 years or older.
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, orthopedist, rheumatologist or physician who specializes in bone disease.
Coverage Duration	1 year
Other Criteria	Fibrodysplasia ossificans progressive-Approve if the patient meets A and B: A)Patient has had a genetic test confirming a mutation in Activin A Type 1 Receptor (ACVR1)R206H consistent with a diagnosis of fibrodysplasia ossificans progressive, AND B) Patient has heterotopic ossification as confirmed by radiologic testing. Note: Examples of radiologic testing are x-ray, computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET) scan.
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

SOLIRIS

Products Affected

- Soliris

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with a rituximab product, Enspryng or Uplizna. Concomitant use with Empaveli for more than 4 weeks.
Required Medical Information	Diagnosis, previous therapies tried, test results
Age Restrictions	neuromyelitis optica, gMG, PNH-18 years and older (initial/continuation)
Prescriber Restrictions	aHUS-prescribed by or in consultation with a nephrologist, gMG-prescribed by or in consultation with a neurologist (initial/cont), neuromyelitis optica (initial/cont)-prescribed by or in consultation with a neurologist, PNH-prescribed by or in consultation with a hematologist (initial/cont)
Coverage Duration	aHUS, neuromyelitis-1 year, gMG/PNH-initial 6 months, cont-1 year
Other Criteria	Atypical Hemolytic Uremic Syndrome (aHUS)-Approve if the patient does not have Shiga toxin E. coli related hemolytic uremic syndrome. Generalized Myasthenia Gravis (gMG)-Initial therapy-approve if the patient meets the following criteria (A, B, C and D):A) Patient has confirmed anti-acetylcholine receptor (AchR) antibody positive generalized Myasthenia Gravis (gMG) AND B) Patient is currently receiving or has tried and has contraindications, intolerance, or failed pyridostigmine, C) Patient has evidence of unresolved symptoms of generalized Myasthenia Gravis (gMG), such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility) AND D) patient has myasthenia gravis foundation of America classification of II to IV and myasthenia gravis activities of daily living (MG-ADL) score of greater than or equal to 6.Continuation-approve if the patient is continuing to derive benefit (e.g., reductions in exacerbations of myasthenia gravis,

PA Criteria	Criteria Details
	improvements in speech, swallowing, mobility, and respiratory function) from Soliris, according to the prescribing physician. Paroxysmal Nocturnal Hemoglobinuria (PNH)-Initial therapy-Approve if diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages and if the patient has tried Empaveli with inadequate efficacy or significant intolerance. Continuation-approve if the patient is continuing to derive benefit (e.g., stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis) from Soliris, according to the prescribing physician. Neuromyelitis Optica Spectrum disorder initial-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and the patient has a history of at least 1 relapse in the last 12 months or two relapses in the last 2 years. Continuation-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and according to the prescriber, patient has had clinical benefit from the use of Soliris.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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

SORAFENIB

Products Affected

- Nexavar
- 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 1 year.
Other Criteria	Bone cancer, approve if the patient has recurrent chordoma or has osteosarcoma and has tried one standard chemotherapy regimen. GIST, approve if the patient has tried TWO of the following: imatinib mesylate, avapritinib, sunitinib, dasatinib, ripretinib or 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 at least one systemic therapy. AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test and the medication is used in combination with azacitidine or decitabine or patient has had an allogeneic stem cell transplant and is in remission. Renal cell carcinoma (RCC)-approve if the patient has relapsed or advanced clear cell histology and the patient has tried at least one systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and sorafenib is used in combination with topotecan. HCC-approve if the patient has unresectable or metastatic disease. Soft tissue sarcoma-approve if the patient has angiosarcoma or desmoid tumors (aggressive fibromatosis) or solitary fibrous

PA Criteria	Criteria Details
	tumor/hemangiopericytoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. For patients requesting brand Nexavar, approve if the patient has tried generic sorafenib AND brand Nexavar is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the corresponding generic product which, would result in a significant allergy or serious adverse reaction. Please note for all diagnoses: 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	Bone cancer, Soft tissue sarcoma, gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, ovarian, fallopian tube, primary peritoneal cancer, myeloid/lymphoid neoplasms with eosinophilia
Part B Prerequisite	No

SOTYKTU

Products Affected

- Sotyktu

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs). Concurrent use with other potent immunosuppressants, including methotrexate.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial)
Coverage Duration	Initial-3 months, continuation-1 year
Other Criteria	Plaque Psoriasis, initial therapy - Approve if the patient has tried TWO of Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm]Humira, Skyrizi, Stelara SC, Otezla or Taltz. Note: A trial of multiple adalimumab products counts as ONE preferred product. Continuation-approve if the patient experienced a beneficial clinical response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SOVALDI

Products Affected

- Sovaldi oral pellets in packet 150 mg, 200 mg
- Sovaldi oral tablet 200 mg, 400 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Genotype 1 and 4 -18 years or older, Genotype 2 and 3-3 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. And, patients with genotype 1 and 4 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of Sovaldi, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Patients with Genotype 2 and 3 must have a trial of Epclusa or Vosevi prior to approval of Sovaldi, unless Epclusa and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No

SPEVIGO

Products Affected

- Spevigo

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another biologic prescribed for treatment of generalized pustular psoriasis
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	30 days
Other Criteria	Generalized Pustular Psoriasis-Approve if the patient meets the following criteria (A and B): A) Patient is experiencing a flare of a moderate-to-severe intensity and meets all of the following criteria (i, ii, iii, and iv): i. Patient has Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of greater than or equal to 3 points Note: The Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score ranges from 0 [clear skin] to 4 [severe disease], AND ii. Patient has a GPPGA pustulation subscore of greater than or equal to 2 points, AND iii. Patient has new or worsening pustules, AND iv. Patient has erythema and pustules which affects greater than or equal to 5 percent of body surface area, AND B) If patient has already received Spevigo, patient meets both of the following criteria (i and ii): i. Patient has not already received two doses of Spevigo for treatment of the current flare, AND ii. If this is a new flare, at least 12 weeks have elapsed since the last dose of Spevigo.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
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).

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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 1 year.
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	PP-6 years and older (initial therapy).
Prescriber Restrictions	Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy only). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy only). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy only).
Coverage Duration	Approve through 12/31/24.
Other Criteria	PP initial - Approve Stelara SC if the patient has tried one traditional systemic agent for psoriasis for at least 3 months unless intolerant or if the patient has a contraindication to methotrexate. Note: Examples of traditional systemic agents used for psoriasis include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. 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, adalimumb, infliximab) OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas

PA Criteria	Criteria Details
	OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). CD, initial therapy subcutaneous (only after receiving single IV loading dose within 2 months of initiating therapy with Stelara SC) - approve 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 onventional 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, induction therapy, approve if the patient has tried one systemic agent for ulcerative colitis or if the patient has pouchitis and has tried an antibiotic, probiotic, corticosteroid enema or mesalamine enema. UC, initial therapy subcutaneous-before the SC formulation can be approved the patient must have received a single IV loading dose within 2 months of initiating therapy with Stelara SC and try one systemic agent for ulcerative colitis or if the patient has pouchitis and has tried an antibiotic, probiotic, corticosteroid enema or mesalamine enema. 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

STIMUFEND

Products Affected

- Stimufend

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. Radiation Syndrome -1 mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 % based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, OR the patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. For all diagnoses except hematopoietic subsyndrome of acute radiation syndrome: Patients are required to try Ziextenzo and Nyvepria prior to approval of Stimufend.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
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	1 year
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/Appendiceal cancer-approve if the patient has advanced or metastatic disease, has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient meets one of the following (i or ii): i. patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type), the patient has tried Erbitux or Vectibix or the patient's tumor did not originate on the left side of the colon (from the splenic fixture to rectum) or ii. the patient's tumor or metastases has a RAS mutation (either KRAS mutation or NRAS mutation). Glioblastoma-approve if the patient has recurrent disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Soft tissue Sarcoma, Osteosarcoma, Glioblastoma, Appendiceal cancer
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.

PA Criteria	Criteria Details
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 meets the following criteria (A and B): A) The diagnosis is established by one of the following (i or ii): i. Patient has endoscopic biopsy of the small bowel with disaccharidase levels consistent with congenital sucrose-isomaltase deficiency as evidenced by ALL of the following (a, b, c, and d): a) Decreased (usually absent) sucrase (normal reference: greater than 25 U/g protein), b) Decreased to normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein], c) Decreased maltase (normal reference: greater than 100 U/g protein), d) Decreased to normal lactase (normal reference: greater than 15 U/g protein) OR ii. Patient has a molecular genetic test demonstrating homozygous or compound heterozygous pathogenic or likely pathogenic sucrase-isomaltase gene variant AND B) Patient has symptomatic congenital sucrose-isomaltase deficiency (e.g., diarrhea, bloating, abdominal cramping).
Indications	All FDA-approved Indications.

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

SUNITINIB

Products Affected

- sunitinib malate
- Sutent

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	1 year
Other Criteria	Gastrointestinal stromal tumors (GIST), approve if the patient has tried imatinib or Ayvakit or if the patient has succinate dehydrogenase (SDH)-deficient GIST. 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 at least one systemic therapy. Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried at least one systemic chemotherapy. 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 advanced disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease. Pheochromocytoma/paraganglioma-approve if the patient has unresectable or metastatic disease. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. For patients requesting brand Sutent, approve if the patient has tried generic sunitinib AND brand Sutent is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives]

PA Criteria	Criteria Details
	between the Brand and the corresponding generic product which, would result in a significant allergy or serious adverse reaction.
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, pheochromocytoma/paraganglioma, myeloid/lymphoid neoplasms with eosinophilia, GIST-unresectable succinate dehydrogenase (SDH)-deficient GIST, or use after avapritinib.
Part B Prerequisite	No

SUNOSI

Products Affected

- Sunosi

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Sunosi with Xyrem (sodium oxybate oral solution), Xywav (calcium, magnesium, potassium, and sodium oxybates oral solution), and/or Wakix (pitolisant tablets)
Required Medical Information	Diagnosis
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 Obstructive Sleep Apnea-Approve if the patient has tried generic modafinil or generic armodafinil. Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or Nuvigil. Excessive daytime sleepiness associated with Narcolepsy-Approve if patient has been evaluated using polysomnography and a multiple sleep latency test (MSLT) and the diagnosis of narcolepsy has been confirmed and if the patient has tried generic modafinil or generic armodafinil. Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or Nuvigil.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SYFOVRE

Products Affected

- Syfovre

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	Authorization will be for 1 year.
Other Criteria	Geographic Atrophy-approve if the patient has geographic atrophy secondary to age-related macular degeneration and the patient has a best corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	1 year
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 1 year.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has advanced or 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

TADALAFIL

Products Affected

- Cialis oral tablet 2.5 mg, 5 mg
- tadalafil oral tablet 2.5 mg, 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Indication for which tadalafil is being prescribed.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 mos.
Other Criteria	Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TADLIQ

Products Affected

- Tadliq

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, right heart cath results
Age Restrictions	N/A
Prescriber Restrictions	For PAH, prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	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. Patient must have tried generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets unless the patient cannot swallow or has difficulty swallowing generic sildenafil 20 mg tablets Alyq or generic tadalafil 20 mg tablets or if the patient requires administration of a dose that cannot be obtained with generic tadalafil 20 mg tablets.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAFAMIDIS

Products Affected

- Vyndamax
- Vyndaqel

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	1 year and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
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 postive 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 one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c, or d): a)

PA Criteria	Criteria Details
	glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma OR d)Oligodendroglioma 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 (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) 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. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer-approve if the patient meets the following (A, B, and C): A) Patient has recurrent disease, AND B) Patient has BRAF V600 mutation-positive disease, AND C) The medication will be taken in combination with Mekinist (trametinib tablets).
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, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
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	1 year
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 disease and has received previous adjuvant chemotherapy or if the patient is inegligible 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

PA Criteria	Criteria Details
Part B Prerequisite	No

TAKHZYRO

Products Affected

- Takhzyro

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda)
Required Medical Information	Diagnosis, lab values
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 (initial and continuation).
Coverage Duration	1 year
Other Criteria	Prophylaxis, initial therapy-approve if the patient meets all of the following criteria: 1) patient has HAE due to C1 Inhibitor (C1-INH) deficiency (Type I or II), AND 2) patient has low levels of functional C1-INH protein (less than 60 percent of normal) at baseline, as defined by the laboratory reference values, AND 3) patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Prophylaxis, continuation therapy-approve if the patient meets all of the following criteria: 1) patient is currently receiving Takhzyro for HAE type I or II, AND 2) according to the prescribing physician, the patient has had a favorable clinical response to therapy (e.g., decrease in number of HAE acute attack frequency, decrease in HAE attack severity, decrease in duration of HAE attacks).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
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	Approve through 12/31/24.
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-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.

PA Criteria	Criteria Details
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

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	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

TARPEYO

Products Affected

- Tarpeyo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	10 months total therapy
Other Criteria	Primary Immunoglobulin A Nephropathy-Initial therapy-Approve if the patient meets the following criteria (i, ii, iii, and iv): i. Diagnosis has been confirmed by biopsy, AND ii. Patient is at high risk of disease progression and meets a and b: proteinuria greater than 0.75 g/day OR urine protein-to-creatinine ratio greater than or equal to 0.8 g/g, AND b) patient has been receiving the maximum or maximally tolerated dose of an angiotensin converting enzyme (ACS) inhibitor OR angiotensin receptor blocker (ARB) for greater than or equal to 90 days, AND iii. Patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73 m2, AND iv. Patient has not previously been treated with Tarpeyo Note: For a patient currently receiving Tarpeyo, review using continuation criteria. Continuation of therapy-approve if the patient meets the following criteria (i, ii, and iii): i. Diagnosis has been confirmed by biopsy, AND ii. Patient has been receiving the maximum or maximally tolerated dose of an ACE inhibitor or ARB for greater than or equal to 90 days, AND iii. Patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73 m2.

PA Criteria	Criteria Details
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	Patients new to therapy with Acute lymphoblastic leukemia, philadelphia chromosome positive or chronic myeloid leukemia- approve if the patient has tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafinib or ripretinib. 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.

PA Criteria	Criteria Details
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.
Part B Prerequisite	No

TAVALISSE

Products Affected

- Tavalisse

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies or surgeries
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by, or in consultation with a hematologist (initial therapy)
Coverage Duration	Initial-3 months, cont-1 year
Other Criteria	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 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

TAVNEOS

Products Affected

- Tavneos

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist (initial)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, initial-approve if the patient meets (i, ii, iii and iv): i. Patient has granulomatosis with polyangiitis or microscopic polyangiitis, Note: Granulomatosis with polyangiitis is also known as Wegener's granulomatosis AND ii. Patient has active disease, Note: This includes patients that have newly diagnosed or relapsed disease. This does not include patients already in remission. AND iii. Patient is positive for proteinase 3 antibodies, or anti-neutrophil cytoplasmic autoantibody (ANCA) or myeloperoxidase antibodies, AND iv. Patient is using this medication in combination with at least one immunosuppressant Note: Examples of immunosuppressants include methotrexate, rituximab, azathioprine, or mycophenolate mofetil. Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, continuation-approve if the patient meets at least one of the following (a or b): a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Tavneos), OR Note: Examples of objective measure include improvement in estimated glomerular filtration rate, decrease in urinary albumin creatinine ratio, or improvement

PA Criteria	Criteria Details
	in the Birmingham Vasculitis Activity Score [BVAS]. b) Compared with baseline (prior to receiving Tavneos), patient experienced an improvement in at least one symptom, such as joint pain, ulcers, myalgia, persistent cough, skin rash or abdominal pain, or improvement in function or activities of daily living.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAZAROTENE

Products Affected

- Arazlo
- Fabior
- tazarotene topical cream
- tazarotene topical foam
- tazarotene topical gel
- Tazorac

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	1 year
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 there are no appropriate alternative therapies or 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

TEGSEDI

Products Affected

- Tegsedi

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Onpattro or a Tafamidis product
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
Coverage Duration	1 year
Other Criteria	Approve if the patient has a documented transthyretin (TTR) mutation verified by genetic testing and the patient has symptomatic polyneuropathy (e.g., reduced motor strength/coordination, impaired sensation [e.g., pain, temperature, vibration, touch]).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TEPEZZA

Products Affected

- Tepezza

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 ophthalmologist, endocrinologist, or a physician who specializes in thyroid eye disease.
Coverage Duration	6 months, up to 8 total doses max
Other Criteria	Thyroid Eye Disease-approve if the patient has not received 8 doses (total) of Tepezza. Note-the maximum recommended treatment is for 8 doses.
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	1 year
Other Criteria	NSCLC-approve if the patient has advanced or 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

- Forteo
- teriparatide subcutaneous pen injector 20 mcg/dose (600mcg/2.4mL)
- teriparatide subcutaneous pen injector 20 mcg/dose (620mcg/2.48mL)

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,

PA Criteria	Criteria Details
	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. If the request is for brand name Forteo, patients must have a trial of teriparatide first. Patients who 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
- Xenazine 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. If the brand is requested the patient must have tried and cannot take generic tetrabenazine tablets as identified by the prescribing physician.
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

TEZSPIRE

Products Affected

- Tezspire

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Tezspire with another monoclonal antibody therapy
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist, pulmonologist
Coverage Duration	Initial- 6 months, Continuation-1 year
Other Criteria	Asthma, initial-approve if the patient meets the following criteria (i and ii): i. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following: an inhaled corticosteroid and at least one additional asthma controller or asthma maintenance medication, ii. Patient has asthma that is uncontrolled or was uncontrolled at baseline (baseline is defined as prior to receiving Tezspire or another monoclonal antibody therapy for asthma) as defined by ONE of the following (a, b, c, d, or e): a) Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, OR b) Patient experienced one or more asthma exacerbation(s) requiring hospitalization, an Emergency Department visit, or an urgent care 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 has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy AND Note: Baseline is defined as prior to receiving any Tezspire, anti-interleukin-5 therapies (i.e., Cinqair, Fasenra, or Nucala), Dupixent, or Xolair. Asthma, continuation-approve if the patient has received at least 6 months of therapy with

PA Criteria	Criteria Details
	Tezspire (patient who has received less than 6 months of therapy or who is restarting therapy should be reviewed under initial therapy), patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler and the patient has responded to therapy. For all covered diagnoses the patient must have a trial of Dupixent, Fasenra, Nucala or Xolair (if the patient has not tried Dupixent, Fasenra, Nucala or Xolair a trial of Cinqair would also count towards meeting this requirement). A trial of Dupixent, Fasenra, Nucala or Xolair is not required if the patient has already been started on therapy with Tezspire or if the prescriber states, based on the asthma phenotype, the patient is not a candidate for one of these medications.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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 1 year.
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

PA Criteria	Criteria Details
	has multicentric Castleman's disease, is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
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	1 year
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. Myelodysplastic Syndrome-approve if patient has isocitrate dehydrogenase-1 (IDH1) mutation-positive disease AND relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chondrosarcoma, Central nervous system cancer

PA Criteria	Criteria Details
Part B Prerequisite	No

TIOPRONIN

Products Affected

- Thiola
- Thiola EC
- tiopronin

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, weight, laboratory testing, therapies tried
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a nephrologist, urologist, or physician who specializes in the treatment of cystinuria
Coverage Duration	Authorization will be for 1 year
Other Criteria	Cystinuria- approve if the patient weighs greater than or equal to 20 kilograms AND cystinuria has been confirmed based on laboratory testing (e.g., urinary cystine crystals present on microscopy, quantitative urine cystine assay) AND patient has had an inadequate response to high fluid intake, dietary modification, and urinary alkalization.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

- Bethkis
- Kitabis Pak
- Tobi
- 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

TOLCAPONE

Products Affected

- Tasmar oral tablet 100 mg
- tolcapone

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, current medications and medication history (as described in Other Criteria)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's disease-approve if the patient is currently receiving carbidopa/levodopa therapy and the patient has tried entacapone and according to the prescriber, experienced significant intolerance or inadequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOLSURA

Products Affected

- Tolsura

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, current medications and medication history (as described in Other Criteria)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	Blastomycosis-pulmonary or extrapulmonary, treatment, Histoplasmosis (Including Chronic Cavitary Pulmonary Disease and Disseminated, Non-Meningeal)-treatment, Aspergillosis-pulmonary or extrapulmonary, treatment-approve if the patient has tried itraconazole capsules or oral solution OR if the patient is currently receiving Tolsura for the diagnosis provided
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOLVAPTAN

Products Affected

- Samsca
- 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

- Elidel
- Eucrisa
- 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 ALPHA-ADRENERGIC AGENTS FOR ROSACEA

Products Affected

- brimonidine topical
- Mirvaso
- Rhofade

PA Criteria	Criteria Details
Exclusion Criteria	Use in the treatment of erythema not caused by rosacea (ie, transient) [eg, during times of stress, sunburn, or skin irritation from cosmetic products].
Required Medical Information	N/A
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOPICAL RETINOID PRODUCTS

Products Affected

- adapalene topical cream
- adapalene topical gel 0.3 %
- adapalene topical gel with pump
- adapalene topical solution
- adapalene topical swab
- adapalene-benzoyl peroxide
- Aklief
- Altreno
- Atralin
- clindamycin-tretinoin
- Differin topical cream
- Differin topical gel with pump
- Differin topical lotion
- Epiduo Forte
- Epiduo topical gel with pump
- Retin-A
- Retin-A Micro
- tretinoin microspheres
- tretinoin topical
- Twyneo
- Veltin
- Ziana

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
- Qudexy XR
- Topamax
- topiramate
- Trokendi XR
- Zonegran oral capsule 100 mg, 25 mg
- 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

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.

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

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

- fentanyl citrate buccal lozenge on a handle
- fentanyl citrate buccal tablet, effervescent
- Fentora

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

TRASTUZUMAB

Products Affected

- Herceptin Hylecta
- Herceptin intravenous recon soln 150 mg
- Herzuma
- Kanjinti
- Ogivri
- Ontruzant

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. Patients new to therapy, requesting Herceptin, Herzuma, Kanjinti, Ogivri or Ontruzant must have a trial of Trazimera 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 new to therapy, requesting Herceptin Hylecta must have a trial of Trazimera and cannot continue to use this product or if there is an inability to obtain or maintain intravenous access a trial of Trazimera will not be required.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Biliary tract cancer, colon or rectal cancer, endometrial carcinoma, salivary gland tumor

PA Criteria	Criteria Details
Part B Prerequisite	No

TRELSTAR

Products Affected

- Trelstar intramuscular suspension for reconstitution

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 oncologist or urologist
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

TREMFYA

Products Affected

- Tremfya

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Previous medication use
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy). PsA-prescribed by or in consultation with a dermatologist or rheumatologist (initial therapy).
Coverage Duration	Approve through 12/31/24.
Other Criteria	PP-Initial Therapy - Approve if the patient has tried TWO of the following: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Skyrizi, Stelara SC, Otezla, or Taltz. A trial of multiple adalimumab products counts as ONE preferred product. PsA-Approve if the patient has tried TWO of the following: Enbrel, an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm], Taltz, Stelara, Rinvoq, Skyrizi, Otezla, Orencia or Xeljanz/XR (Please note-a trial of Cimzia, a non-preferred adalimumab, Simponi and Cosentyx would also count towards the try TWO requirement). A trial of multiple adalimumab products counts as ONE preferred product.) Continuation Therapy - Patient must have responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

TRIENTINE

Products Affected

- Cuvrior
- Syprine
- trientine oral capsule 250 mg
- trientine oral capsule 500 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medication history, pregnancy status, disease manifestations (all as described in Other Criteria)
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)

PA Criteria	Criteria Details
	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
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	1 year
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

TRUQAP

Products Affected

- Truqap

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-Approve if the patient meets the following (A, B, C, D and E): A) Patient has locally advanced or metastatic disease, AND B) Patient has hormone receptor positive (HR+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has at least one phosphatidylinositol 3-kinase (PIK3CA), serine/threonine protein kinase (AKT1), or phosphatase and tensin homolog (PTEN)-alteration, AND E) Patient meets one of the following (i or ii): i. Patient has had progression with at least one endocrine-based regimen in the metastatic setting (Note: Examples of endocrine therapy include anastrozole, exemestane, and letrozole.) OR ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRUXIMA

Products Affected

- Truxima

PA Criteria	Criteria Details
Exclusion Criteria	Rituximab will not be used concurrently with another biologic or with a targeted synthetic DMARD (RA diagnosis)-initial therapy
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	RA-prescribed by or in consultation with a rheumatologist (initial therapy)
Coverage Duration	RA-1 month, all others-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. RA-initial therapy-approve if the patient has tried ONE conventional synthetic disease-modifying Antirheumatic drug (DMARD) for at least 3 months. Note-if the patient has already had a 3-month trial of at least one biologic, these patients are not required to step back and try a conventional synthetic DMARD. Continuation-approve if 16 weeks or more will elapse between treatment courses and if the patient has already received two or more courses of therapy, the patient has responded to therapy as determined by the prescriber. Patients are required to try Ruxience prior to approval of Truxima unless the patient has already been started on or has previously received Truxima, or if the patient has a diagnosis of Rheumatoid arthritis (RA).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
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	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast Cancer-approve if the patient has recurrent 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	1 year
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

TYMLOS

Products Affected

- Tymlos

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

PA Criteria	Criteria Details
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 Briumvi or Kesimpta unless the patient meets one of the following: patient has previously received a highly effective therapy in the past (i.e. Tysabri, Tyruko, Briumvi, Ocrevus, Kesimpta, Mavenclad or Lemtrada) OR the patient has active hepatitis B virus infection OR 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.Continuation-approve. Adults with CD, initial. Patient has

PA Criteria	Criteria Details
	moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein) and patient has tried two of the following agents for CD for at least 2 months each: adalimumab, certolizumab pegol, infliximab, vedolizumab, ustekinzumab, OR pt has had an inadequate response or was intolerant to these agents. CD, continuation therapy. Patient has had a response to Tysabri, as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TYVASO DPI

Products Affected

- Tyvaso DPI

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with oral or parenteral prostacyclin agents used for pulmonary hypertension
Required Medical Information	Diagnosis
Age Restrictions	Pulmonary Hypertension w/Interstitial lung disease - 18 years and older (intial/cont)
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist or a pulmonologist (initial and continuation).
Coverage Duration	PAH, WHO Group 1-1 year (initial/cont). Pulmonary HTN w/lung disease-Initial-4 months, cont-1 year
Other Criteria	PAH, WHO Group 1, initial therapy-approve if the patient has had a right heart catheterization to confirm the diagnosis and if the patient meets i or ii: i. Patient has Functional Class III or IV or, ii. Patient is in Functional Class II and the patient has tried or is currently receiving one of Opsumit, Adempas or Uptravi OR the patient has tried one inhaled or parenteral prostacyclin product for PAH. A trial of any other endothelin receptor antagonist, PDE5 inhibitor, inhaled prostacyclin product or oral prostacyclin product would also count if the patient has not tried Opsumit, Adempas Or Uptravi. Continuation-approve if the patient has had a right heart catheterization to confirm the diagnosis. Pulmonary Hypertension associated with interstitial lung disease, WHO Group 3 (this involves diagnosis such as idiopathic interstitial pneumonia, combined pulmonary fibrosis and emphysema, WHO Group 3 connective disease and chronic hypersensitivity pneumonitis), initial therapy - approve if the patient has had a right heart catheterization to confirm the diagnosis and has connective tissue disease with a baseline forced vital capacity less than 70 percent and the patient has evidence of diffuse parenchymal lung disease

PA Criteria	Criteria Details
	on computed tomography of the chest. Continuation- approve if the patient has had a right heart catheterization to confirm the diagnosis and has had a response to therapy.
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

UDENYCA

Products Affected

- Udenyca
- Udenyca Autoinjector
- Udenyca Onbody

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/Radiation Syndrome-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if - the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia 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. Patients are required to try Ziextenzo and Nyvepria prior to approval of Udenyca. Hematopoietic subsyndrome of acute radiation syndrome-approve.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No

ULTOMIRIS

Products Affected

- Ultomiris intravenous solution 100 mg/mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another complement inhibitor or Vyvgart-IV. Concurrent use with another complement inhibitor-SC
Required Medical Information	Diagnosis, test results
Age Restrictions	aHUS/PNH-18 years and older (init/cont, SC formulation only), MG-18 years and older (initial/cont)
Prescriber Restrictions	PNH-Prescribed by or in consultation with a hematologist (initial/cont). aHUS-prescribed by or in consultation with a nephrologist. MG-prescribed by or in consultation with a neurologist (initial/cont).
Coverage Duration	PNH/MG-Initial 6 months, cont-1 year, aHUS-1 year
Other Criteria	PNH-Initial therapy-Approve if diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages and patients must have a trial of Empaveli with inadequate efficacy or significant intolerance unless the patient is less than 18 years of age. In addition, for subcutaneous formulation-patient has received or will receive Ultomiris IV infusion loading dose prior to initiation of Ultomiris subcutaneous. Continuation-approve if the patient is continuing to derive benefit (e.g., stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis) from Ultomiris, according to the prescribing physician.aHUS-approve if the patient does not have Shiga toxin E. coli related hemolytic uremic syndrome. In addition, for subcutaneous formulation-patient has received or will receive Ultomiris IV infusion loading dose prior to initiation of Ultomiris subcutaneous. Generalized Myasthenia Gravis (gMG)-Initial therapy-approve if the patient meets the following criteria (A, B, C and

PA Criteria	Criteria Details
	D):A) Patient has confirmed anti-acetylcholine receptor (AchR) antibody positive generalized Myasthenia Gravis (gMG) AND B) Patient is currently receiving or has tried and has contraindications, intolerance, or failed pyridostigmine, AND C) Patient has evidence of unresolved symptoms of generalized Myasthenia Gravis (gMG), such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility) AND D) patient has myasthenia gravis foundation of America classification of II to IV and myasthenia gravis activities of daily living (MG-ADL) score of greater than or equal to 6. Continuation-approve if the patient is continuing to derive benefit (e.g., reductions in exacerbations of myasthenia gravis, improvements in speech, swallowing, mobility, and respiratory function) from Ultomiris, according to the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

UPLIZNA

Products Affected

- Uplizna

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with a rituximab product, Enspryng or Soliris
Required Medical Information	Diagnosis
Age Restrictions	NMOSD-18 years and older (initial and continuation)
Prescriber Restrictions	NMOSD-prescribed by or in consultation with a neurologist (initial and continuation)
Coverage Duration	NMOSD-1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Neuromyelitis Optica Spectrum Disorder initial-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and patient has a history of at least 1 relapse in the last 12 months or two relapses in the last 2 years. Continuation-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and according to the prescriber, patient has had clinical benefit from the use of Uplizna.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

UPTRAVI

Products Affected

- Uptravi

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.
Required Medical Information	Confirmation of right heart catheterization, medication history (as described in Other Criteria)
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 Uptravi 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

VABYSMO

Products Affected

- Vabysmo

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	Macular Edema following Retinal Vein Occlusion - 6 mos., all other dx - 1 year
Other Criteria	N/A
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	1 year
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 antiseizure medication(s).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VANCOMYCIN

Products Affected

- Vancocin oral capsule 125 mg, 250 mg
- 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

VELSIPITY

Products Affected

- Velsipity

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs) for ulcerative colitis.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	1 year
Other Criteria	Ulcerative colitis, initial therapy-approve if the patient has had a trial of BOTH: an adalimumab product [i.e., Humira, Cyltezo, adalimumab adbm, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz] AND Stelara. A trial of an infliximab product (Remicade, biosimilars, Zymfentra), Simponi SC, Entyvio IV/SC, Omvoh IV/SC, or a Non-Preferred adalimumab product will also count. Ulcerative colitis, continuation-approve if the patient has had a response.
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	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML-approve if used in combination with azacitidine, decitabine, or cytarabine. CLL/SLL- approve. Mantle Cell Lymphoma- approve if the patient has tried at least one systemic regimen. Multiple Myeloma- approve if the patient has t (11,14) translocation AND has tried at least one systemic regimen for multiple myeloma AND Venclexta will be used in combination with dexamethasone. Systemic light chain amyloidosis-approve if the patient has t (11, 14) translocation and has tried at least one systemic regimen. Waldenstrom acroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient 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

VEOZAH

Products Affected

- Veozah

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.
Off-Label Uses	N/A
Part B Prerequisite	No

VERKAZIA

Products Affected

- Verkazia

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	4 years and older
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist
Coverage Duration	1 year
Other Criteria	Vernal keratoconjunctivitis-approve if the patient has moderate to severe vernal keratoconjunctivitis and patient meets one of the following (i or ii): i. Patient has tried two single-action ophthalmic medications (i.e., ophthalmic mast-cell stabilizers or ophthalmic antihistamines) for the maintenance treatment of vernal keratoconjunctivitis Note: Examples of single-action ophthalmic medications for the maintenance treatment of vernal keratoconjunctivitis include ophthalmic mast-cell stabilizers (e.g., cromolyn ophthalmic solution, Alomide ophthalmic solution]) and ophthalmic antihistamines (e.g., Zerviate [cetirizine solution]), OR ii. Patient has tried one dual-action ophthalmic mast-cell stabilizer/antihistamine product for the maintenance treatment of vernal keratoconjunctivitis. Note: Examples of dual-action ophthalmic mast-cell stabilizer/antihistamine products include azelastine ophthalmic solution, beoptastine ophthalmic solution, epinastine ophthalmic solution, ketotifen ophthalmic solution, Lastacaft, and olopatadine ophthalmic solution. Note: An exception to the requirement for a trial of two single-action ophthalmic medications (i.e., ophthalmic mast-cell stabilizers or ophthalmic antihistamines) or one dual-action ophthalmic mast-cell

PA Criteria	Criteria Details
	stabilizer/antihistamine product for the maintenance treatment of vernal keratoconjunctivitis can be made if the patient has already tried at least one ophthalmic cyclosporine product (e.g., Cequa [cyclosporine 0.09% ophthalmic solution], Restasis [cyclosporine 0.05% ophthalmic emulsion]) other than the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	1 year
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 has node-positive disease at high risk of recurrence 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/perimenopausal 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/perimenopausal 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.
Off-Label Uses	N/A
Part B Prerequisite	No

VIGABATRIN

Products Affected

- Sabril
- vigabatrin
- Vigadrone
- Vigpoder

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medication history (complex partial seizures)
Age Restrictions	Refractory complex partial seizures - patients 2 years of age or older. Infantile spasms - patients less than or equal to 2 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist
Coverage Duration	Infantile spasms- 6 mo. Treatment-Refractory Partial Seizures-initial therapy 3 mo, cont-1 year
Other Criteria	Infantile spasms-requested medication is being used as monotherapy. Treatment refractory complex partial seizures intial-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Treatment refractory complex partial seizures continuation- the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VIJOICE

Products Affected

- Vijoice oral tablet 125 mg, 250 mg/day (200 mg x1-50 mg x1), 50 mg

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 a physician that specializes in treatment of genetic disorder (initial therapy)
Coverage Duration	Initial-6 months, continuation- 1 year
Other Criteria	PIK3CA-Related Overgrowth Spectrum (PROS), initial therapy-Approve if the patient has at least one severe clinical manifestation of PROS and the patient has a PIK3CA mutation as confirmed by genetic testing Note: Examples of severe clinical manifestations include excessive tissue growth, blood vessel malformations, scoliosis, vascular tumors, cardiac or renal manifestations, and those that require systemic treatment. PIK3CA-Related Overgrowth Spectrum (PROS), continuation-Approve if the patient has been established on Vijoice for at least 6 months and has experienced a reduction in volume from baseline (prior to initiating Vijoice) in at least one lesion as confirmed by measurement and has experienced an improvement in at least one sign or symptom of PROS from baseline (prior to initiating Vijoice) Note: Examples of signs or symptoms of PROS include pain, fatigue, vascular malformation, limb asymmetry, or disseminated intravascular coagulation.
Indications	All FDA-approved Indications.

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

VILTEPSO

Products Affected

- Viltepso

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 physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	DMD- patient has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	1 year
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

VIVJOA

Products Affected

- Vivjoa

PA Criteria	Criteria Details
Exclusion Criteria	Patients must not be pregnant or breastfeeding or have reproductive potential (a person who is NOT of reproductive potential is defined as a person who is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy)
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Monotherapy-12 weeks, Combination use with fluconazole-14 weeks
Other Criteria	Recurrent vulvovaginal candidiasis, initial therapy-approve if the patient has had at least three episodes of vulvovaginal candidiasis in a 12-month period and has tried oral fluconazole as maintenance therapy and had inadequate efficacy [Note: Maintenance dosing should be for 30 days], OR Patient meets one of the following (a, b, or c): a. Oral fluconazole is not clinically appropriate for the patient due to drug-drug interactions, as determined by the prescriber, OR b. Patient has a fluconazole allergy or intolerance, as determined by the prescriber, OR c. Patient is being treated for a Candida species that is not susceptible to fluconazole, as determined by the prescriber. Recurrent vulvovaginal candidiasis, continuation-approve if the patient has already started on Vivjoa therapy (to complete the course of treatment).
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
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	1 year
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	1 year
Other Criteria	Myelofibrosis (MF), including primary MF, post-polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient meets either (A or B): (A) the patient has a platelet count of less than 50 X 109 /L (less than 50,000/mcL) and meets one of the following criteria (a or b):a) Patient has intermediate-risk or high-risk disease and is not a candidate for transplant, or b)Patient has lower-risk disease and has tried at least one prior therapy OR (B) Patient has a platelet count of greater than or equal to 50 X 109 /L (greater than or equal to 50,000/mcL) and meets all of the following criteria (a, b and c): a) Patient has high-risk disease, AND b) Patient is not a candidate for transplant, AND c) Patient has tried Jakafi (ruxolitinib tablets) or Inrebic (fedratinib capsules).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VORICONAZOLE (ORAL)

Products Affected

- Vfend
- 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

- pazopanib
- Votrient

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	1 year
Other Criteria	Soft tissue sarcoma other than GIST-approve if the patient has advanced or metastatic disease and has ONE of the following: alveolar soft part sarcoma, angiosarcoma, desmoid tumors (aggressive fibromatosis, dermatofibrosarcoma protuberans with fibrosarcomatous transformation, non-adipocytic sarcoma or pleomorphic rhabdomyosarcoma. 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 or metastatic disease. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or advanced disease or VonHippel-Lindau 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 succinate dehydrogenase (SDH)-deficient GIST OR the patient has tried TWO of the following: Gleevec, Ayvakit, Sutent, Sprycel, Qinlock or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried at least one systemic therapy. Bone cancer-approve if the patient has chondrosarcoma and has metastatic widespread disease.

PA Criteria	Criteria Details
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, bone cancer.
Part B Prerequisite	No

VOXZOGO

Products Affected

- Voxzogo

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent treatment with growth hormone (e.g., somatropin), long acting growth hormone (e.g., lonapegsomatropin), or insulin-like growth factor-1 (IGF-1) [i.e., Increlex]
Required Medical Information	Diagnosis
Age Restrictions	Less than 18 years old (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	Achondroplasia-approve if the patient meets ONE of the following criteria (A or B): A) Initial Therapy or Patient Has Been on Voxzogo less than 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, and iv): i. The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, AND ii. Patient's epiphyses are open, AND iii. Patient will not have limb-lengthening surgery during treatment with Voxzogo, AND iv. The prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration B) Patient Has Been Receiving Voxzogo for greater than or equal to 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v): i. The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, AND ii. Patient's epiphyses are open, AND iii. Patient will not have limb-lengthening surgery during treatment with Voxzogo, AND iv. The prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration, AND

PA Criteria	Criteria Details
	v. Patient's most recent annualized growth velocity continues to be above their baseline annualized growth velocity value (i.e., before the patient started on Voxzogo).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VPRIV

Products Affected

- VPRIV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic tests and lab 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	Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VTAMA

Products Affected

- Vtama

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 dermatologist
Coverage Duration	1 year
Other Criteria	Plaque Psoriasis-patient meets ALL of the following criteria (A, B and C): A) Patient has psoriasis involvement estimated to affect less than or equal to 20 percent of the body surface area, AND B) Patient meets one of the following criteria (i or ii): i. Patient meets all of the following criteria (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 this topical corticosteroid, according to the prescriber, OR ii. Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia, AND C) Patient meets ALL of the following criteria (i and ii): i. Patient has tried at least one topical vitamin D analog, AND (Note: Examples of topical vitamin D analogs include calcipotriene 0.005% foam (Sorilux, authorized generic), calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% ointment (generic only), calcitriol 3 mcg/g ointment (Vectical, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% foam (Enstilar) , calcipotriene 0.005% and betamethasone dipropionate 0.064% cream (Wynzora), calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex, generic),

PA Criteria	Criteria Details
	calcipotriene 0.005% and betamethasone dipropionate 0.064% suspension (Taclonex, generic. Concomitant use of a topical vitamin d analog and a topical corticosteroid would meet the requirement), ii. Inadequate efficacy was demonstrated with this topical vitamin D analog.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VUITY

Products Affected

- Vuity

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

VYEPTI

Products Affected

- Vyepti

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Aimovig, Ajovy or Emgality
Required Medical Information	Diagnosis, prior therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Approve if the patient has tried TWO of the following: Aimovig, Ajovy or Emgality.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VYJUVEK

Products Affected

- Vyjuvek

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	6 months and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or wound care specialist
Coverage Duration	6 months
Other Criteria	Dystrophic epidermolysis bullosa-approve if the diagnosis is confirmed by genetic testing showing a pathogenic mutation in the collagen type VII alpha 1 chain (COL7A1) gene, AND the patient has at least one clinical feature of dystrophic epidermolysis bullosa, AND the patient has one or more open wounds. Note: Examples of clinical features of dystrophic epidermolysis bullosa include but are not limited to blistering, wounds, and scarring.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VYONDYS

Products Affected

- Vyondys-53

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 physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	DMD- patient has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VYVGART

Products Affected

- Vyvgart
- Vyvgart Hytrulo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial and continuation)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	Generalized myasthenia gravis, Initial Therapy-Approve if the patient meets the following criteria (A, B, C and D): A. Patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis, AND B. Patient received or is currently receiving pyridostigmine or has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine, C. Patient has evidence of unresolved symptoms of generalized myasthenia gravis, such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility) AND D) patient has myasthenia gravis foundation of america classification of II to IV and myasthenia gravis activities of daily living (MG-ADL) score of greater than or equal to 5. Generalized myasthenia gravis, Continuation Therapy-Approve if patient is continuing to derive benefit from Vyvgart. All treatment cycles should be no more frequent than every 50 days from the start of the previous treatment cycle.
Indications	All FDA-approved Indications.

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

WAKIX

Products Affected

- Wakix

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Wakix with Xyrem (sodium oxybate oral solution), Xywav (calcium, magnesium, potassium, and sodium oxybates oral solution), and/or Sunosi (solriamfetol tablets).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consult with a sleep specialist physician or a neurologist
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Excessive daytime sleepiness associated with Narcolepsy-Approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT) AND the patient has tried generic modafinil or generic armodafinil (Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or Nuvigil) OR patient has a history of substance use disorder and a wakefulness-promoting agent that is not a controlled substance is necessary, per the prescriber. Cataplexy treatment in patients with narcolepsy-approve if the patient has been evaluated using polysomnography and a multiple sleep latency test (MSLT) and the diagnosis of narcolepsy has been confirmed.
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	1 year
Other Criteria	Renal Cell Carcinoma- approve if pt has advanced disease AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND has tried at least one a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). [Note: Examples of PD-1 inhibitor or PD-L1 inhibitor include: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Bavencio (avelumab intravenous infusion). Examples of VEGF-TKI include Cabometyx (cabozantinib tablets), Lenvima (lenvatinib capsules), Inlyta (axitinib tablets), Fotivda (tivozanib capsules), pazopanib, sunitinib, and sorafenib.] 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.

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

WINLEVI

Products Affected

- Winlevi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Acne vulgaris-Approve if the patient has tried one prescription topical retinoid and one other prescription topical therapy (e.g., dapsone gel, Azelex, topical clindamycin, topical erythromycin, topical minocycline).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XALKORI

Products Affected

- Xalkori oral capsule
- Xalkori oral pellet 150 mg, 20 mg, 50 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Anaplastic large cell lymphoma/IMT-patients greater than or equal to 1 year of age. All other diagnoses-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
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 and patients new to therapy must have a trial of Alecensa prior to approval of Xalkori. Metastatic non-small cell lung cancer, approve if the patient has 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 (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt 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. Inflammatory Myofibroblastic Tumor-approve if the patient has ALK positive disease and the patient has advanced, recurrent or metastatic disease or the tumor is

PA Criteria	Criteria Details
	inoperable. 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.
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	Approve through 12/31/24.
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]-

PA Criteria	Criteria Details
	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 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

XENPOZYME

Products Affected

- Xenpozyme

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 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	Acid Sphingomyelinase Deficiency (ASMD)-Approve if the patient meets the following criteria (A, B, and C): A) The diagnosis of ASMD is established by (i, ii and iii): i. acid sphingomylinase (ASM) enzymatic assay testing and, ii. confirmed by mutation testing, and iii. the diagnosis of Gaucher disease has been excluded AND B) Patient meets ONE of the following criteria (i or ii): i. Patient has ASMD type B, OR ii. Patient has ASMD type A/B, AND C) Patient has two or more non-central nervous system signs of ASMD type B or type A/B (e.g., hepatosplenomegaly, interstitial lung disease, decreased diffusing capacity of the lungs, progressive liver disease with cirrhosis or fibrosis, dyslipidemia, osteopenia, thrombocytopenia, anemia, leukopenia).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XEOMIN

Products Affected

- Xeomin

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for cosmetic uses
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.
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 for Peyronie's Disease (i.e., treatment beyond eight injections).
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 as part of the current treatment course. 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

PA Criteria	Criteria Details
Part B Prerequisite	No

XOLAIR

Products Affected

- Xolair subcutaneous auto-injector 150 mg/mL, 300 mg/2 mL, 75 mg/0.5 mL
- Xolair subcutaneous recon soln
- Xolair subcutaneous syringe 150 mg/mL, 300 mg/2 mL, 75 mg/0.5 mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy.
Required Medical Information	Moderate to severe persistent asthma baseline (defined as prior to receiving any treatment with Xolair or another monoclonal antibody that may lower IgE levels) IgE level of at least 30 IU/mL. For asthma, patient has a baseline (baseline is defined as prior to receiving any Xolair or another monoclonal antibody that may interfere with allergen testing) 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

PA Criteria	Criteria Details
	corticosteroid and at least one additional asthma controller or asthma maintenance medication (Examples: LABA, LAMA, leukotriene receptor antagonist, monoclonal antibody therapies for asthma), and 2) patient's asthma is uncontrolled or was uncontrolled prior to receiving Xolair or another monoclonal antibody therapy for asthma 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 hospitalization, urgent care visit 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 (defined as prior to receiving any treatment with Xolair oa another monoclonal antibody therapy that may lower IgE) 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	1 year
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

XPHOZAH

Products Affected

- Xphozah

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a nephrologist
Coverage Duration	1 year
Other Criteria	Hyperphosphatemia in chronic kidney disease: approve if the patient meets all of the following (A, B, C and D): (A) the patient has chronic kidney disease (CKD), (B) patient has been on maintenance dialysis for at least 3 months, (C) patient serum phosphate level is greater than or equal to 5.5 mg/dL and less than 10.0 mg/dL, (D) patient meets one of the following (i or ii): (i) patient has tried at least two phosphate binders [examples include sevelamer, lanthanum, ferric citrate, and sucroferric oxyhydroxide, calcium carbonate, and calcium acetate] and had an inadequate response and/or intolerance to at least two phosphate binders OR (ii) patient meets either (a or b): (a) patient has a contraindication to at least two phosphate binders [examples include bowel obstruction, iron overload, or hypercalcemia], or (b) patient has inadequate response and/or intolerance to at least one phosphate binder and a contraindication to at least one phosphate binder.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
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	1 year
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-

PA Criteria	Criteria Details
	CD38 monoclonal antibody. Diffuse large B-cell lymphoma Note:this includes patients with histologic transformation of indolent lymphomas to 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.
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 1 year.
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. Prostate cancer- Non-Metastatic, Castration-Sensitive - approve if pt has biochemical recurrence and is at high risk for metastasis. [Note: High-risk biochemical recurrence is defined as prostate-specific antigen (PSA) doubling time less than or equal to 9 months.]
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XURIDEN

Products Affected

- Xuriden

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic specialist, geneticist or physician specializing in the condition being treated
Coverage Duration	1 year
Other Criteria	Hereditary orotic aciduria (Orotic aciduria Type 1)-Approve if the patient has molecular genetic testing confirming biallelic pathogenic mutations in the UMPS gene or clinical diagnosis supported by at least one clinical manifestation consistent with orotic aciduria type 1, first degree family relative (i.e., parent or sibling) with hereditary orotic aciduria and urinary orotic acid level above the normal reference range for the reporting laboratory.
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 (as described in Other Criteria field)
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

XYWAV

Products Affected

- Xywav

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of sodium oxybate, Xyrem, Wakix, Sunosi
Required Medical Information	Medication history (as described in Other Criteria field)
Age Restrictions	Narcolepsy-7 years and older, Idiopathic hypersomnia-18 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 - 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). Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Idiopathic hypersomnia-approve if the diagnosis has been confirmed using polysomnography and a multiple sleep latency test and if the patient has tried modafinil.
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	1 year
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, ii or iii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) agonist OR ii. The patient has had a bilateral orchiectomy or iii. the medication is concurrently used with Firmagon.
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 - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT- 3mo.other=12mo. Radi-1 mo.
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

PA Criteria	Criteria Details
	frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).
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. Acute lymphocytic leukemia (ALL). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome)
Part B Prerequisite	No

ZAVZPRET

Products Affected

- Zavzpret

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 if the patient has tried Nurtec and one triptan, unless the patient has a contraindication to triptans. Note: Examples of contraindications to triptans include a history of coronary artery disease, cardiac accessory conduction pathway disorders, history of stroke, transient ischemic attack, or hemiplegic or basilar migraine, peripheral vascular disease, ischemic bowel disease, uncontrolled hypertension, or severe hepatic impairment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	1 year
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 and if the patient is in complete or partial response to first-line primary treatment or if the patient has recurrent disease and a BRCA mutation. 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

ZELAPAR

Products Affected

- Zelapar

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medication history (as described in Other Criteria)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's Disease-approve if the patient is experiencing off episodes such as muscle stiffness, slow movements or difficulty starting movements, is currently receiving carbidopa/levodopa therapy and has tried oral selegiline tablets/capsules or rasagiline tablets and according to the prescriber had significant intolerance or has difficulty swallowing tablets/or capsules.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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 1 year.
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 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 one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a or b): a) glioma OR b) 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 (i, ii, or iii): i.

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

ZEPATIER

Products Affected

- Zepatier

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin or Sovaldi.
Required Medical Information	Genotype, prior medication therapy, concurrent medications, NS5A polymorphism status, prescriber specialty
Age Restrictions	12 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or liver transplant MD.
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1 and genotype 4 must have a trial with Harvoni, Vosevi or Epclusa prior to approval of Zepatier, unless Harvoni, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Patients who are 12 and older but less than 18 are not required to try Vosevi.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
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 an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz, adalimumab-adbm]. Note-a trial of Simponi SC, a non-preferred adalimumab product 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.

PA Criteria	Criteria Details
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No

ZOKINVY

Products Affected

- Zokinvy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results
Age Restrictions	12 months and older
Prescriber Restrictions	Prescribed by or in consultation with a geneticist or cardiologist
Coverage Duration	1 year
Other Criteria	Hutchinson-Gilford Progeria Syndrome, approve if the patient meets (A and B): A) Patient has a body surface area greater than or equal to 0.39 m2 B) Genetic testing demonstrates a confirmed pathogenic mutation in the LMNA gene consistent with Hutchinson-Gilford Progeria Syndrome. Progeroid laminopathies, approve if the patient meets (A and B): A) Patient has a body surface area greater than or equal to 0.39 m2 B) Patient has Heterozygous LMNA mutation with progerin-like protein accumulation or Homozygous or compound heterozygous ZMPSTE24 mutations.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	1 year
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

ZORYVE

Products Affected

- Zoryve topical cream

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	6 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	1 year
Other Criteria	Plaque Psoriasis-patient meets ALL of the following criteria (A, B and C): A) Patient has psoriasis involvement estimated to affect less than or equal to 20 percent of the body surface area, AND B) Patient meets one of the following criteria (i or ii): i. Patient meets all of the following criteria (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 this topical corticosteroid, OR ii. Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia, AND C) Patient meets ALL of the following criteria (i and ii): i. Patient has tried at least one topical vitamin D analog, AND Note: Examples of topical vitamin D analogs include calcipotriene 0.005% foam (Sorilux, authorized generic), calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% ointment (generic only), calcitriol 3 mcg/g ointment (Vectical, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% foam (Enstilar) , calcipotriene 0.005% and betamethasone dipropionate 0.064% cream (Wynzora), calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex, generic), calcipotriene 0.005% and betamethasone dipropionate

PA Criteria	Criteria Details
	0.064% suspension (Taclonex, generic. Concomitant use of a topical vitamin d analog and a topical corticosteroid would meet the requirement ii. Inadequate efficacy was demonstrated with this topical vitamin D analog.
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 and patient has tried or is concomitantly receiving two other antiepileptic drugs.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZURZUVAE

Products Affected

- Zurzuvae

PA Criteria	Criteria Details
Exclusion Criteria	Previous treatment with Zurzuvae during the current episode of postpartum depression
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist
Coverage Duration	14 days
Other Criteria	Postpartum depression-approve if the patient meets the following (A, B and C): A.Patient meets BOTH of the following (i and ii): i. Patient has been diagnosed with severe depression, AND ii. Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery, AND B. Patient is less than or equal to 12 months postpartum, AND C. Patient is not currently pregnant.
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 1 year.
Other Criteria	CLL/SLL-approve if the patient has tried at least one systemic regimen.
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	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Erdheim-Chester Disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. NSCLC, ALK positive-approve if the patient has advanced or metastatic disease that is ALK positive as detected by an approved test and for patients new to therapy must have a trial of Alecensa prior to approval of Zykadia. NSCLC, ROS1 Rearrangement-approve if the patient has advanced or metastatic disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	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. Large B-Cell Lymphoma and HIV-Related B-Cell Lymphoma-approve if the patient has tried at least two systemic regimens.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	HIV-related B-Cell Lymphoma
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
- Zytiga oral tablet 250 mg, 500 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	Authorization will be for 1 year.
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

PA Criteria	Criteria Details
	prednisone, 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 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
- Adriamycin intravenous recon soln 50 mg
- Aggrastat Concentrate
- Aggrastat in sodium chloride
- albuterol sulfate inhalation solution for nebulization
- Alimta
- Aliqopa
- Alkeran
- Alkeran (as HCl)
- AmBisome
- amiodarone intravenous
- amphotericin B
- amphotericin B liposome
- Anzemet oral tablet 50 mg
- aprepitant
- arformoterol
- Arranon
- arsenic trioxide
- Astagraf XL
- Atgam
- azacitidine
- Azasan
- azathioprine
- azathioprine sodium
- baclofen intrathecal
- Bavencio
- Beleodaq
- bendamustine intravenous recon soln
- bendamustine intravenous solution
- Bendeka
- Besponsa
- BiCNU
- bleomycin
- Blincyto intravenous kit
- bortezomib injection recon soln 1 mg, 2.5 mg
- bortezomib injection recon soln 3.5 mg
- Brovana
- budesonide inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
- busulfan
- Busulfex
- Camptosar
- carboplatin intravenous solution
- carmustine intravenous recon soln 100 mg
- CellCept
- CellCept Intravenous
- 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)
- Clinimix E 2.75%/D5W Sulf Free
- Clinimix E 4.25%/D10W Sul Free
- Clinimix E 4.25%/D5W Sulf Free
- Clinimix E 5%/D15W Sulfit Free
- Clinimix E 5%/D20W Sulfit Free
- Clinimix E 8%-D10W sulfitefree
- Clinimix E 8%-D14W sulfitefree
- Clinisol SF 15 %
- Clinolipid
- clofarabine
- Clolar
- Cosmegen
- cromolyn inhalation
- Cutaquig
- Cuvitru
- cyclophosphamide intravenous recon soln
- cyclophosphamide intravenous solution
- cyclophosphamide oral capsule
- cyclophosphamide oral tablet
- cyclosporine intravenous
- cyclosporine modified
- cyclosporine oral capsule

- Cyramza
- cytarabine
- cytarabine (PF)
- CytoGam intravenous solution 50 mg/mL
- dacarbazine
- Dacogen
- dactinomycin
- Darzalex
- Darzalex Faspro
- daunorubicin
- decitabine
- deferoxamine
- Desferal
- 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)
- Doxil
- doxorubicin
- doxorubicin, peg-liposomal
- dronabinol
- Duopa
- Ellence
- Emend oral capsule 80 mg
- Emend oral capsule,dose pack
- Emend oral suspension for reconstitution
- Empliciti
- Engerix-B (PF)
- Engerix-B Pediatric (PF)
- Envarsus XR
- epirubicin intravenous solution 200 mg/100 mL
- epoprostenol
- Erbitux
- Erwinase
- Etopophos
- etoposide intravenous
- everolimus (immunosuppressive)
- Evomela
- Faslodex
- Flolan
- floxuridine
- fludarabine
- fluorouracil intravenous
- Folotyn
- formoterol fumarate
- foscarnet
- fulvestrant
- Gablofen
- 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
- Idamycin PFS
- idarubicin
- Ifex
- ifosfamide
- Imfinzi
- Imuran
- Infugem
- Infumorph P/F
- Intralipid intravenous emulsion 20 %
- Intralipid intravenous emulsion 30 %
- ipratropium bromide inhalation
- ipratropium-albuterol
- irinotecan
- Istodax
- Ixempra
- Jevtana
- Jynneos (PF)
- Kabiven
- Kemoplat
- Khapzory intravenous recon soln 175 mg
- Kyprolis

- leucovorin calcium injection
- levalbuterol HCl
- levoleucovorin calcium
- Lioresal
- Marinol
- Medrol oral tablet 16 mg, 2 mg, 4 mg, 8 mg
- melphalan
- melphalan HCl
- mesna
- Mesnex intravenous
- methotrexate sodium
- methotrexate sodium (PF)
- methylprednisolone oral tablet
- Millipred oral tablet
- milrinone
- milrinone in 5 % dextrose
- mitomycin intravenous
- mitoxantrone
- morphine (PF) intravenous patient control.analgesia soln
- Mozobil
- mycophenolate mofetil
- mycophenolate mofetil (HCl)
- mycophenolate sodium
- Myfortic
- Mylotarg
- Nebupent
- nelarabine
- Neoral
- Nexterone
- Nipent
- 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
- Nutrilipid
- Olinvyk intravenous patient control.analgesia soln
- Omegaven
- Oncaspar
- ondansetron
- ondansetron HCl oral solution
- ondansetron HCl oral tablet 4 mg, 8 mg
- Onivyde
- Orapred ODT
- oxaliplatin
- paclitaxel
- paclitaxel protein-bound
- Paraplatin
- Pedmark
- pemetrexed disodium intravenous recon soln 1,000 mg, 100 mg, 500 mg
- pemetrexed disodium intravenous recon soln 750 mg
- pemetrexed disodium intravenous solution
- pemetrexed intravenous recon soln 100 mg, 500 mg
- pentamidine inhalation
- Perforomist
- Perikabiven
- Perjeta
- Plenamine
- plerixafor
- Portrazza
- pralatrexate
- prednisolone oral tablet
- prednisolone sodium phosphate oral tablet,disintegrating
- Prehevbrio (PF)
- Premasol 10 %
- Prialt
- Prograf
- Prosol 20 %
- Pulmicort inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
- Pulmozyme
- Rapamune
- Recombivax HB (PF)
- romidepsin intravenous recon soln
- romidepsin intravenous solution
- Sandimmune
- Simulect
- sirolimus
- SMOFlipid
- sodium nitroprusside
- Sylvant
- Syndros
- tacrolimus oral

- Tecentriq
- Temodar intravenous
- temsirolimus
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- thiotepa
- Thymoglobulin
- Tice BCG
- tirofiban-0.9% sodium chloride
- topotecan
- Torisel
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- Veletri
- Ventavis
- Vidaza
- vinblastine
- vincristine
- vinorelbine
- Vyxeos
- Xatmep
- Xembify
- Xgeva
- Yervoy
- Yondelis
- Yupelri
- Zaltrap
- Zanosar
- Zirabev
- zoledronic acid intravenous solution
- zoledronic acid-mannitol-water intravenous piggyback 4 mg/100 mL
- zoledronic ac-mannitol-0.9NaCl
- Zortress

Details

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

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