

## ACTEMRA

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### Products Affected

- ACTEMRA INTRAVENOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	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, a preferred adalimumab product, 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, Kevzara, infliximab, golimumab SC/IV, or a non-preferred adalimumab product will also count.). 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, Rinvoq, Xeljanz or a preferred adalimumab product. (Note: if the patient does not meet this requirement, a previous trial with the drug Kevzara, infliximab or a non-preferred adalimumab product will be counted towards meeting the try TWO requirement.), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Systemic-onset JIA, approve. Giant cell arteritis, initial-approve if the patient has tried or is currently taking a systemic corticosteroid or corticosteroid is contraindicated. Cont tx, RA/PJIA/SJIA/GCA - approve if the pt had a response as determined by

<b>PA Criteria</b>	<b>Criteria Details</b>
	the prescriber. Cytokine release syndrome associated with chimeric antigen receptor (CAR) T-Cell therapy-approve. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ACTEMRA SQ

## Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS
- TYENNE AUTOINJECTOR
- TYENNE SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	Interstitial lung disease-18 years and older (initial and continuation)
<b>Prescriber Restrictions</b>	RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA) [A or B]: A) tried two of the following: Enbrel, preferred adalimumab product (see Example 1), Orencia, Rinvoq or Xeljanz/XR (Note: trials with the following will also count towards meeting the try two requirement: Cimzia, infliximab, Kevzara, golimumab SC/IV, non-preferred adalimumab product), or B) heart failure or a previously treated lymphoproliferative disorder. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A or B]: A) tried two of the following: Enbrel, Orencia, Rinvoq, Xeljanz, preferred adalimumab product. (Note: trials with Kevzara, infliximab or a non-preferred adalimumab product will also count towards meeting the try two requirement), or B) heart failure or a previously treated lymphoproliferative disorder. SYSTEMIC-ONSET JIA (SJIA): Approve. GIANT CELL ARTERITIS: tried or is currently taking a systemic CS or CS is contraindicated. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) elevated acute phase reactants and B) diagnosis confirmed by high-resolution computed tomography. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Example 1: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma.
<b>Indications</b>	All FDA-approved Indications.

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

# ACTHAR

## Products Affected

- ACTHAR
- ACTHAR SELFJECT

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	Infantile spasms - approve if Acthar is being administered as intramuscular injection. 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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ACTIMMUNE

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## Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Chronic granulomatous disease - prescribed by or in consultation with an immunologist, hematologist or infectious disease specialist. Malignant osteopetrosis- prescribed by or in consultation with an endocrinologist or hematologist.
Coverage Duration	1 year
Other Criteria	Chronic granulomatous disease - approve if diagnosis has been established by a molecular genetic test identifying a gene-related mutation linked to chronic granulomatous disease. Malignant osteopetrosis, severe - approve if pt has had radiographic (X-ray) imaging demonstrating skeletal features related to osteopetrosis or pt had a molecular genetic test identifying a gene-related mutation linked to severe, malignant osteopetrosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ACYCLOVIR (TOPICAL)

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## Products Affected

- *acyclovir topical cream*
- *acyclovir topical ointment*
- ZOVIRAX TOPICAL CREAM
- ZOVIRAX TOPICAL OINTMENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medication history (as described in Other Criteria field)
<b>Age Restrictions</b>	Acyclovir 5 percent cream, 12 yrs or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ADAKVEO

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## 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

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## Products Affected

- ABRILADA(CF) PEN
- ABRILADA(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.4 ML, 40 MG/0.8 ML
- ADALIMUMAB-AACF SUBCUTANEOUS PEN INJECTOR KIT
- ADALIMUMAB-AACF SUBCUTANEOUS SYRINGE KIT
- ADALIMUMAB-AACF(CF) PEN CROHNS
- ADALIMUMAB-AACF(CF) PEN PS-UV
- ADALIMUMAB-AATY SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- ADALIMUMAB-AATY SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML
- ADALIMUMAB-AATY(CF) AI CROHNS
- ADALIMUMAB-ADAZ SUBCUTANEOUS PEN INJECTOR 40 MG/0.4 ML, 80 MG/0.8 ML
- ADALIMUMAB-ADAZ SUBCUTANEOUS SYRINGE 10 MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML
- ADALIMUMAB-ADBM (PREFERRED NDCS STARTING WITH 00597) SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML, 40 MG/0.8 ML
- ADALIMUMAB-ADBM (PREFERRED NDCS STARTING WITH 00597) SUBCUTANEOUS SYRINGE KIT 10 MG/0.2 ML, 20 MG/0.4 ML, 40 MG/0.4 ML, 40 MG/0.8 ML
- ADALIMUMAB-FKJP SUBCUTANEOUS PEN INJECTOR KIT
- ADALIMUMAB-FKJP SUBCUTANEOUS SYRINGE KIT 20 MG/0.4 ML, 40 MG/0.8 ML
- ADALIMUMAB-RYVK SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- ADALIMUMAB-RYVK SUBCUTANEOUS SYRINGE KIT
- 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
- CYLTEZO(CF) PEN
- CYLTEZO(CF) PEN CROHN'S-UC-HS SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.8 ML
- CYLTEZO(CF) PEN PSORIASIS-UV SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.8 ML
- CYLTEZO(CF) SUBCUTANEOUS SYRINGE KIT 10 MG/0.2 ML, 20 MG/0.4 ML, 40 MG/0.4 ML, 40 MG/0.8 ML
- HADLIMA
- HADLIMA PUSH TOUCH
- HADLIMA(CF)
- HADLIMA(CF) PUSH TOUCH
- HULIO(CF) PEN SUBCUTANEOUS PEN INJECTOR KIT
- HULIO(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.4 ML, 40 MG/0.8 ML
- HUMIRA (PREFERRED NDCS STARTING WITH 00074) SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML
- HUMIRA PEN (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) PEN (PREFERRED NDCS STARTING WITH 00074) SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- HUMIRA(CF) PEN CROHN'S-UC-HS (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) PEN PSOR-UV-ADOL HS (PREFERRED NDCS STARTING WITH 00074)
- HYRIMOZ (PREFERRED NDCS STARTING WITH 61314)
- HYRIMOZ PEN (PREFERRED NDCS STARTING WITH 61314)
- HYRIMOZ PEN CROHN'S-UC STARTER (PREFERRED NDCS STARTING WITH 61314)
- HYRIMOZ PEN PSORIASIS STARTER (PREFERRED NDCS STARTING WITH 61314)
- 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(CF) PEDI CROHN STARTER (PREFERRED NDCS STARTING WITH 61314) SUBCUTANEOUS SYRINGE 80 MG/0.8 ML, 80 MG/0.8 ML- 40 MG/0.4 ML
- HYRIMOZ(CF) PEN (PREFERRED NDCS STARTING WITH 61314)
- IDACIO(CF) PEN CROHN-UC STARTER
- IDACIO(CF) PEN PSORIASIS STARTER
- IDACIO(CF) PEN SUBCUTANEOUS PEN INJECTOR KIT
- SIMLANDI(CF) AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- SIMLANDI(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML, 80 MG/0.8 ML
- 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 20 MG/0.2 ML, 40 MG/0.4 ML
- YUSIMRY(CF) PEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Initial therapy only: Crohn's disease (CD)-6 or older, Ulcerative colitis (UC)-5 or older, PP/ Pyoderma gangrenosum/ sarcoidosis/ scleritis/non-radiographic axial spondyloarthritis-18 years and older, Behcet's disease-2 years and older
<b>Prescriber Restrictions</b>	Initial therapy only for all dx, prescribed by or in consultation with one of the following specialists-RA/JIA/JRA/Ankylosing spondylitis/nr-axSpA, rheumatologist. PsA, rheumatologist or dermatologist. PP, dermatologist. UC/ CD, gastroenterologist. HS/pyoderma gangrenosum - dermatologist.UV/scleritis-ophthalmologist. Behcet's- rheum, dermatologist, ophthalmologist, gastro, neuro. Sarcoidosis, pulm, ophthalmologist, dermatologist.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Behcet's disease, pyoderma gangrenosum, sarcoidosis, scleritis, non-radiographic axial spondyloarthritis.
<b>Part B Prerequisite</b>	No

# ADBRY

## Products Affected

- ADBRY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another monoclonal antibody therapy (i.e., Dupixent, Cinqair, Fasenra, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical].
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	AD-12 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
<b>Coverage Duration</b>	Initial-Atopic Dermatitis-4 months, Continuation-1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ADEMPAS

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## 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

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## 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 initial therapy if the patient meets (A and B): 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. Non-Muscle Invasive Bladder Cancer, continuation of therapy - approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ADZYNMA

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## 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

# AGAMREE

## Products Affected

- AGAMREE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years of age and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders (initial/continuation)
Coverage Duration	1 year
Other Criteria	<p>Duchenne muscular dystrophy, initial therapy-Approve if the patient meets the following (i and ii): i. Patient's diagnosis of Duchenne Muscular Dystrophy is confirmed by one of the following (a or b): a) Genetic testing with a confirmed pathogenic variant in the dystrophin gene, OR b) Muscle biopsy showing the absence of, or marked decrease in, dystrophin protein, AND ii. Patient meets ONE of the following (a or b): a) Patient has tried prednisone or prednisolone for 90 days AND the patient has had treatment failure or had at least one of the following significant intolerable adverse effects [1, 2, 3, or 4]: 1) Cushingoid appearance, OR 2) Central (truncal) obesity, OR 3) Undesirable weight gain defined as greater than or equal to 10 percent body weight increase over a 6-month period, OR 4) Diabetes and/or hypertension that is difficult to manage according to the prescriber, OR b) The patient has experienced a severe behavioral adverse event while on prednisone or prednisolone therapy that has or would require a prednisone or prednisolone dose reduction. Duchenne muscular dystrophy, continuation therapy, Approve if the patient meets the following (i and ii): i. Patient has tried prednisone or prednisolone, AND ii. The patient has responded to or continues to have improvement or benefit from Agamree therapy. Note: Examples of improvement or benefit from Agamree therapy would include improvements in motor function (e.g., time from supine to standing, time to climb four stairs, time to run or walk 10 meters, 6-minute</p>



<b>PA Criteria</b>	<b>Criteria Details</b>
	walk test), improvement in muscle strength, and improved pulmonary function.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# AIMOVIG

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## Products Affected

- AIMOVIG AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with another cGRP inhibitor for migraine headache prevention
Required Medical Information	Diagnosis, number of migraine headaches per month
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) If pt is currently taking Aimovig, the pt has had significant clinical benefit from the medication.
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 another cGRP inhibitor for migraine headache prevention
Required Medical Information	Diagnosis, number of migraine headaches per month, prior therapies tried
Age Restrictions	6 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine headache prevention in adults: Approve if the patient meets the following criteria (A, B and C): 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 Emgality and Aimovig, AND C) if the pt is currently taking Ajovy, the pt has had significant clinical benefit. Preventive treatment of episodic migraine in pediatric patients: Approve if the patient meets the following criteria (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), and B) if the pt is currently taking Ajovy, the pt has had significant clinical benefit. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Ajovy was initiated.
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

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## 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 biallelic pathogenic or likely pathogenic alpha-L-iduronidase gene variants.
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	Pediatric diffuse high grade glioma- less than or equal to 21 years old, All others- 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Non-small cell lung cancer-approve if the patient has both (A and B): A) either (i or ii): i) medication is used as adjuvant treatment following tumor resection (note: for tumors greater than or equal to 4 cm or node positive) or ii) advanced or metastatic disease and B) 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. Pediatric diffuse high grade glioma- approve if (A and B): A) ALK-positive disease, and B) either (i or ii): i) medication is used as adjunctive treatment AND tumor is not diffuse midline glioma, H3 K27-altered or pontine location, or ii) medication is used for recurrent or progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma, Pediatric Diffuse High Grade Glioma
<b>Part B Prerequisite</b>	No

# ALOSETRON

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## 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

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## Products Affected

- ARALAST NP
- GLASSIA
- PROLASTIN-C INTRAVENOUS SOLUTION
- 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 or Lorbrena prior to approval of Alunbrig. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT), Peripheral T-Cell Lymphoma
Part B Prerequisite	No

# ALVAIZ

## Products Affected

- ALVAIZ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Aplastic anemia/Thrombo w/Hep C-18 years and older, Immune thrombocytopenia-6 years and older
Prescriber Restrictions	Immune Thrombo/AA-presc or consult heme(initial).Thrombo/Hep C-prescr or consult gastro, hepatologist, physician specializing in infectious disease. MDS-presc or consult heme/onc(initial).Post-trans-presc or consult heme/onc/stem cell transplant specialist physician (initial)
Coverage Duration	Immune thrombo/MDS init-3 mo,cont 1yr, AA-init-4 mo,cont-1 yr,Thrombo/Hep C-1 yr, transplant-6 mo.
Other Criteria	Thrombocytopenia in patients with immune thrombocytopenia, initial - approve if the patient has a platelet count less than 30 x 10 <sup>9</sup> /L (less than 30,000/mcL) or less than 50 x 10 <sup>9</sup> /L (less than 50,000/mcL) and the patient is at an increased risk for bleeding AND has tried ONE other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate, Tavalisse, Doptelet, rituximab) or has undergone a splenectomy. Immune thrombocytopenia, 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 - approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND if the patient has low platelet counts at baseline (pretreatment) Note: An example of a low platelet count is less than 75 x 10 <sup>9</sup> /L (less than 75,000/mcL). Aplastic anemia, initial - approve if the patient has low platelet counts at baseline (pretreatment) AND patient tried one immunosuppressant therapy OR patient will be using Alvaiz in combination with standard immunosuppressive therapy. Aplastic anemia, cont-approve if the patient demonstrates a beneficial clinical response. Note: An example of a low platelet count is less than 30 x 10 <sup>9</sup> /L (less than 30,000/mcL). Thrombocytopenia in a patient with Myelodysplastic

PA Criteria	Criteria Details
	<p>syndrome (MDS)-initial, approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than <math>30 \times 10^9/L</math> (less than 30,000/mcL) or less than <math>50 \times 10^9/L</math> (less than 50,000/mcL) and is at an increased risk for bleeding. Thrombocytopenia in a pt with MDS, Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Thrombocytopenia in post allogeneic transplantation, initial-approve if the patient has poor graft function and has a platelet count less than <math>50 \times 10^9/L</math> (less than 50,000/mcL). Cont-approve if the patient demonstrates a beneficial clinical response. In addition, for new starts and all covered diagnoses, patients must have a trial of Promacta prior to approval of Alvaiz.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Thrombocytopenia in Myelodysplastic Syndrome (MDS), Thrombocytopenia in a patient post -allogeneic transplantation
<b>Part B Prerequisite</b>	No

# ALYFTREK

## Products Affected

- ALYFTREK ORAL TABLET 10-50-125 MG, 4-20-50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with unknown cystic fibrosis transmembrane conductance regulator gene mutation. Combination therapy with other cystic fibrosis transmembrane conductance regulator modulators.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	6 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>CYSTIC FIBROSIS - All of (A, B and C): A) Patient has at least one mutation in the cystic fibrosis conductance regulator gene that is considered to be a pathogenic or likely pathogenic variant, AND B) Patient meets at least ONE of the following (i, ii, or iii): i. Positive cystic fibrosis newborn screening test, OR ii. Family history of cystic fibrosis, OR iii. Clinical presentation consistent with signs and symptoms of cystic fibrosis, Note: Examples of clinical presentation of cystic fibrosis include but are not limited to meconium ileus, sino-pulmonary symptoms (e.g., persistent cough, wheezing, pulmonary function tests consistent with obstructive airway disease, excess sputum production), bronchiectasis, sinusitis, failure to thrive, pancreatic insufficiency, AND C) Patient has evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by at least ONE of the following (i, ii, or iii): i. Elevated sweat chloride test, OR ii. Two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations, OR iii. Abnormal nasal potential difference.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# AMONDYS

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## 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
<b>Exclusion Criteria</b>	Concomitant use with Onpattro (patisiran intravenous injection), Tegsedi (inotersen subcutaneous injection), Wainua (eplontersen subcutaneous injection) or a Tafamidis Product
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	hATTR: Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis. ATTR-CM: prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR)-approve if the patient meets (A, B and C)-A) Patient has a transthyretin pathogenic variant 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. Cardiomyopathy of Wild-Type or Hereditary Transthyretin-Mediated Amyloidosis (ATTR-CM)-approve if the patient meets (A, B and C): A) diagnosis has been confirmed by one of (i, ii or iii): i) technetium pyrophosphate scan (i.e., nuclear scintigraphy), or ii) tissue biopsy with confirmatory transthyretin (TTR) amyloid typing by mass spectrometry, immunoelectron microscopy or immunohistochemistry, or iii) genetic testing which, according to the prescriber, identified a transthyretin (TTR) pathogenic variant, and B) diagnostic cardiac imaging has demonstrated cardiac involvement, and C) pt has heart failure, but does not have New York Heart Association class IV disease.</p>



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

# ANDEMBRY

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## Products Affected

- ANDEMBRY AUTOINJECTOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other Hereditary Angioedema (HAE) prophylactic therapies.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	HEREDITARY ANGIOEDEMA (HAE) DUE TO C1 INHIBITOR (C1-INH) DEFICIENCY-PROPHYLAXIS-HAE type I or type II as confirmed by the following diagnostic criteria (a and b): Note: A diagnosis of HAE with normal C1-INH (also known as HAE type III) does NOT satisfy this requirement. a)Low levels of functional C1-INH protein (less than or equal to 50 percent of normal) at baseline, as defined by the laboratory reference values, AND b) Lower than normal serum C4 levels at baseline, as defined by the laboratory reference values.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ANKTIVA

## Products Affected

- ANKTIVA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist (initial/maintenance therapy)
Coverage Duration	Initial-6 months, Maintenance-3 months
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. INITIAL-NON-MUSCLE INVASIVE BLADDER CANCER-all of (i, ii, iii): i) Patient has Bacillus Calmette-Guerin (BCG) unresponsive disease, AND ii) Patient has carcinoma in situ with or without papillary tumors, AND iii) Medication is used in combination with BCG. MAINTENANCE THERAPY-NON-MUSCLE INVASIVE BLADDER CANCER-all of (i and ii): i) Patient has an ongoing complete response defined as ONE of the following (a or b): a) Patient has negative cystoscopy and meets ONE of the following [(1) or (2)]: 1. Negative urine cytology, OR 2. Malignant urine cytology if cancer found in the upper tract or prostatic urethra and random bladder biopsies are negative, OR b) Patient has positive cystoscopy with biopsy-proven benign or low-grade Ta non-muscle invasive bladder cancer and negative urine cytology, AND ii) Medication is used in combination with BCG.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

## ANTIBIOTICS (IV)

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### Products Affected

- *amikacin injection solution 1,000 mg/4 ml, 500 mg/2 ml*
- *ampicillin sodium injection recon soln 1 gram, 10 gram, 2 gram, 250 mg, 500 mg*
- *ampicillin sodium intravenous*
- *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*
- *colistin (colistimethate na)*
- COLY-MYCIN M PARENTERAL
- *dalbavancin*
- DALVANCE
- *doxy-100*
- *doxycycline hyclate intravenous*
- EMBLAVEO
- *ertapenem*
- ERYTHROCIN INTRAVENOUS RECON SOLN 500 MG
- *erythromycin lactobionate*
- EXTENCILLINE
- 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*
- *gentamicin sulfate (ped) (pf)*
- *imipenem-cilastatin*
- INVANZ INJECTION
- KIMYRSA
- LENTOCILIN S
- *levofloxacin in d5w*
- *levofloxacin intravenous*
- LINCOCIN
- *lincomycin*
- *linezolid in dextrose 5%*
- LINEZOLID-0.9% SODIUM CHLORIDE
- *meropenem intravenous recon soln 1 gram, 2 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 intravenous piggyback 2 gram/100 ml*
- *nafcillin injection*
- NUZYRA INTRAVENOUS
- ORBACTIV
- *oxacillin*
- *oxacillin in dextrose(iso-osm) intravenous piggyback 2 gram/50 ml*
- PENICILLIN G POT IN DEXTROSE INTRAVENOUS PIGGYBACK 2 MILLION UNIT/50 ML, 3 MILLION UNIT/50 ML
- *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, 1.25 GRAM/250 ML, 1.5 GRAM/300 ML, 500 MG/100 ML, 750 MG/150 ML
- VANCOMYCIN INJECTION
- *vancomycin intravenous recon soln 1,000 mg, 1.25 gram, 1.5 gram, 10 gram, 5 gram, 500 mg, 750 mg*
- VANCOMYCIN INTRAVENOUS RECON SOLN 1.75 GRAM, 2 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
- ZEVTERA
- ZITHROMAX INTRAVENOUS
- ZYVOX INTRAVENOUS PIGGYBACK 600 MG/300 ML

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) intravenous piggyback 200 mg/100 ml, 400 mg/200 ml*
- NOXAFIL INTRAVENOUS
- *posaconazole intravenous*
- VFEND IV
- *voriconazole*
- *voriconazole-hpbcd*

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

# ANZUPGO

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## Products Affected

- ANZUPGO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other JAK inhibitors or with potent immunosuppressants.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist or dermatologist
Coverage Duration	Pending CMS Review
Other Criteria	CHRONIC HAND ECZEMA-all the following (A, B and C): A) Hand eczema that has been present for greater than 3 months or has returned at least twice in a year after its initial presentation and subsequent clearance, AND B) Patient has moderate to severe chronic hand eczema, AND C) Tried at least one medium to super-high-potency prescription topical corticosteroid with inadequate efficacy.
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-HT <sub>3</sub> 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 (e.g., entacapone, rasagiline, pramipexole, ropinirole, tolcapone, selegiline, Ongentys (opicapone capsules), or Xadago (safinamide tablets) and had significant intolerance or inadequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# AQNEURSA

## Products Affected

- AQNEURSA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Miplyffa
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, metabolic disorder subspecialist, neurologist, or a physician who specializes in the treatment of Niemann-Pick disease type C or related disorders (initial and continuation)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	INITIAL, NIEMANN-PICK DISEASE TYPE C - All of (A, B and C): A. Patient weighs greater than or equal to 15 kg, and B. Patient has one or more neurologic symptom(s) of Niemann-Pick disease type C (Note: Examples of neurologic symptoms of Niemann-Pick disease type C are loss of motor function, difficulty swallowing, and speech and cognitive impairment), and C. Diagnosis is established by a genetic test showing biallelic pathogenic variants in either the NPC1 gene or NPC2 gene. CONTINUATION, NIEMANN-PICK DISEASE TYPE C - Patient has derived benefit from treatment defined as disease stabilization, slowed progression, or improvement.
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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	MDS anemia = 18 years of age and older.
<b>Prescriber Restrictions</b>	MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.
<b>Coverage Duration</b>	Anemia w/myelosupp=6 mos, Anemia CKD-1 year, MDS-1 year, Other=6 mos.
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anemia due to myelodysplastic syndrome (MDS)
<b>Part B Prerequisite</b>	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, dermatologist, 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	INITIAL THERAPY: DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) [ all of A, B, and C]: A) weighs at least 10 kg, B) genetic test confirms a mutation in the IL1RN gene, and C) had clinical benefit with anakinra subcutaneous injection. PERICARDITIS: pericarditis is recurrent. CONTINUATION THERAPY: ALL INDICATIONS: patient had a positive response to therapy.
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.
Coverage Duration	1 year
Other Criteria	<p>INITIAL THERAPY: MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE (all of A, B, and C): A) positive sputum culture for MAC [Note: any positive sputum culture taken after completion of a background multidrug regimen (throughout, see Example 1 below) fulfills this criterion], B) MAC isolate is susceptible to amikacin, and C) Arikayce will be used in combination with a background multidrug regimen.</p> <p>CONTINUATION THERAPY: MAC LUNG DISEASE (A and B): A) Arikayce prescribed in combination with a background multidrug regimen and B) patient meets one of the following (a or b): a) patient has not achieved negative sputum cultures for MAC or b) patient has achieved negative sputum cultures for MAC for less than 12 months. Example 1: background multidrug regimen example - a macrolide (azithromycin or clarithromycin), ethambutol, and a rifamycin (rifampin or rifabutin).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ASPARLAS

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## 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

# ATTRUBY

## Products Affected

- ATTRUBY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other medications indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis or transthyretin-mediated amyloidosis-cardiomyopathy (e.g., Amvuttra [vutrisiran subcutaneous injection], Onpattro [patisiran intravenous infusion], Tegsedi [inotersen subcutaneous injection], Wainua [eplontersen subcutaneous injection], or a tafamidis product).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Cardiomyopathy of Wild-Type or Hereditary Transthyretin-Mediated Amyloidosis (ATTR-CM) Note: Variant Transthyretin Amyloidosis is also known as Hereditary Transthyretin Amyloidosis - (all of A, B and C): A. Diagnosis was confirmed by ONE of the following (i, ii, or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy), OR ii. A tissue biopsy with confirmatory transthyretin (TTR) amyloid typing by mass spectrometry, immunoelectron microscopy or immunohistochemistry, OR iii. Genetic testing which identified a transthyretin (TTR) pathogenic variant, Note: Examples of TTR variants include Val122Ile variant and Thr60Ala variant. If the patient has wild-type amyloidosis, this is not a TTR pathogenic variant., AND B. Diagnostic cardiac imaging has demonstrated cardiac involvement, Note: Examples of cardiac imaging include echocardiogram and cardiac magnetic imaging. Examples of cardiac involvement on imaging include increased thickness of the ventricular wall or interventricular septum., AND C. Patient has heart failure, but does not have New York Heart Association class IV disease. In addition to above criteria, patients are required to try Vyndamax or Vyndaqel prior to approval of Attruby.</p>

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



# AUBAGIO

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## 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 ORAL CAPSULE 160 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC - 18 and older, Solid tumors - 12 and older, Pediatric Diffuse High-Grade Glioma-less than 18
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. Note: If the patient has non-small cell lung cancer with neurotrophic receptor tyrosine kinase (NTRK) gene fusion, see Solid Tumors indication. Solid tumors - approve if tumor is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND tumor is locally advanced or metastatic or surgical resection will likely result in severe morbidity. Pediatric Diffuse High-Grade Gliomas - approve if tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used 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 Gliomas
Part B Prerequisite	No

# AUSTEDO

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## Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG, 48 MG, 6 MG
- AUSTEDO XR TITRATION KT(WK1-4) ORAL TABLET, EXT REL 24HR DOSE PACK 12-18-24-30 MG

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

# AVMAPKI-FAKZYNJA

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## Products Affected

- AVMAPKI-FAKZYNJA

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	OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER- ALL of the following (A, B and C): A) Patient has recurrent low-grade serous cancer, AND B) The cancer has a KRAS mutation, AND C) Patient has tried at least one systemic therapy. Note: Examples of systemic therapy include one or more of the following medications: paclitaxel, carboplatin, bevacizumab, letrozole, anastrozole, or exemestane.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Fallopian Tube or Primary Peritoneal Cancer
Part B Prerequisite	No

# AVONEX

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## Products Affected

- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT

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

# AVSOLA

## Products Affected

- AVSOLA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medication, medications previously tried
<b>Age Restrictions</b>	CD/UC - Pts aged 6 years or more (initial therapy). Ulcerative Colitis. PP-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	FDAind ini-3 mo,cont1yr,GVHD ini-1 mo,cont-3 mo,Pyo Gang-ini4 mo,cont1 yr,others-ini 3mo,cont-12 mo
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Behcet's disease, Still's disease, Uveitis, Pyoderma gangrenosum, Hidradenitis suppurativa, Graft-versus-host disease, Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis
<b>Part B Prerequisite</b>	No

# AVTOZMA IV

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## Products Affected

- AVTOZMA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	(Initial therapy only): GCA/RA-18 years and older. PJIA/SJIA-2 years and older.
<b>Prescriber Restrictions</b>	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	ALL DIAGNOSES-approve if patient has tried Tyenne IV AND Actemra IV. A trial of the subcutaneous formulation would also count.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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

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## 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

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## 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 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy, other 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
<b>Exclusion Criteria</b>	Concurrent use with other biologics or Lupkynis
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	5 years and older (initial).
<b>Prescriber Restrictions</b>	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)
<b>Coverage Duration</b>	SLE-Initial-4 months, cont-1 year. Lupus Nephritis-6 mo initial, 1 year cont
<b>Other Criteria</b>	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 Benlysta subcutaneous or intravenous. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA [anti-dsDNA] antibody 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. 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

<b>PA Criteria</b>	<b>Criteria Details</b>
	be intolerant due to a significant toxicity AND The patient has responded to Benlysta subcutaneous or intravenous.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# BENLYSTA IV

## Products Affected

- BENLYSTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	5 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 Benlysta subcutaneous or intravenous. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA [anti-dsDNA] antibody 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. 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

<b>PA Criteria</b>	<b>Criteria Details</b>
	be intolerant due to a significant toxicity AND The patient has responded to Benlysta subcutaneous or intravenous.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# BEOVU

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## Products Affected

- BEOVU

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

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## 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

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## Products Affected

- BETASERON SUBCUTANEOUS KIT

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

# BEVACIZUMAB

## Products Affected

- ALYMSYS
- AVASTIN INTRAVENOUS
- JOBEVNE
- MVASI
- VEGZELMA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older-All diagnoses (except pediatric CNS tumors or ophthalmic conditions)-18 years and older, Pediatric CNS tumor-less than 18
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 Jobevne, 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, medulloblastoma, neurofibromatosis type 2 vestibular schwannomas, vaginal cancer

PA Criteria	Criteria Details
Part B Prerequisite	No

# BEXAROTENE (ORAL)

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## 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. Primary cutaneous B-Cell lymphoma-approve if used as skin-directed therapy for either (a or b): a) primary cutaneous marginal zone lymphoma or b) follicle center lymphoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adult T-Cell Leukemia/Lymphoma, Primary Cutaneous B-Cell Lymphoma
Part B Prerequisite	No

# BIMZELX

## Products Affected

- BIMZELX AUTOINJECTOR  
SUBCUTANEOUS AUTO-INJECTOR  
160 MG/ML, 320 MG/2 ML
- BIMZELX SUBCUTANEOUS  
SYRINGE 160 MG/ML, 320 MG/2 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial)
<b>Prescriber Restrictions</b>	HS/PP: Prescribed by or in consultation with a dermatologist (initial therapy only). AS/NrAxS: Prescribed by or in consultation with a rheumatologist (initial therapy only). PsA: Prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy only).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	Plaque psoriasis, initial therapy-approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi SC, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya, Sotyktu. Ankylosing Spondylitis, initial therapy-approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Rinvoq, Xeljanz/XR, Cosentyx. [A trial of a Non-Preferred adalimumab product, a non-preferred ustekinumab product, Cimzia, Taltz, an infliximab product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.] Non-radiographic axial spondyloarthritis, initial therapy-Approve if the patient has tried Rinvoq or Cosentyx. [A trial of an adalimumab product, Enbrel, Cimzia, Taltz, an infliximab product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.] Psoriatic arthritis, initial therapy-approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Cosentyx, Tremfya, a preferred ustekinumab product, Otezla, Orencia, Rinvoq, Skyrizi or Xeljanz/XR. [A trial of a Non-Preferred adalimumab product, non-preferred ustekinumab, Cimzia, Taltz, an infliximab product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.] Hidradenitis Suppurativa: approve if the patient has tried ONE of the following drugs in the past: a

<b>PA Criteria</b>	<b>Criteria Details</b>
	preferred adalimumab product or Cosentyx SC. A trial of a non-preferred adalimumab also counts. All indications, continuation-approve if the patient has had a response. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# BIZENGRI

## Products Affected

- BIZENGRI

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	<p>NON-SMALL CELL LUNG CANCER-All of (A, B and C): A) Patient has advanced, unresectable, or metastatic disease, AND B) The disease is neuregulin 1 (NRG1) gene fusion positive, AND C) Patient has tried at least one systemic regimen. Note: Examples of a systemic regimen include one or more of the following drugs: carboplatin, cisplatin, or programmed cell death protein 1 (PD)-1 or PD-ligand 1 (PD-L1) blockers.</p> <p>PANCREATIC ADENOCARCINOMA-All of (A, B and C): A) Patient has advanced, unresectable, or metastatic disease, AND B) The disease is neuregulin 1 (NRG1) gene fusion positive, AND C) Patient has tried at least one systemic regimen. Note: Examples of systemic regimen include one or more of the following drugs: fluorouracil, leucovorin, irinotecan, oxaliplatin, gemcitabine, paclitaxel, capecitabine.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No



# BLENREP

## Products Affected

- BLENREP INTRAVENOUS RECON  
SOLN 70 MG

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. Approve if (A, B and C): A) the patient has tried at least two prior systemic lines of therapy and B) has received at least one drug from each of the following drug classes- proteasome inhibitor [ex: bortezomib, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules)] and immunomodulatory drug [ex: lenalidomide, Pomalyst (pomalidomide capsules), and Thalomid (thalidomide capsules], and C) will be used in combination with bortezomib and dexamethasone.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# BONIVA INJECTION

## Products Affected

- *ibandronate intravenous*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other medications for Osteoporosis
Required Medical Information	Diagnosis, test results
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Treatment of postmenopausal osteoporosis, must meet ONE of the following 1. T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, or total hip, 2. has had osteoporotic fracture or fragility fracture, 3. had a T-score (current or at any time in the past) between 1.0 and -2.5 at the lumbar spine, femoral neck, or total hip and the physician determines the patient is at high risk for fracture AND has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of bone mineral density (BMD), lack of BMD increase), had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy, or experienced intolerability to an oral bisphosphonate (e.g., severe GI-related adverse effects) OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid) OR the patient has had an osteoporotic fracture or a fragility fracture.
Indications	All FDA-approved Indications.

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

# BOSENTAN/AMBRISENTAN

## Products Affected

- *ambrisentan*
- *bosentan oral tablet*
- *bosentan oral tablet for suspension*
- LETAIRIS
- TRACLEER ORAL TABLET
- TRACLEER ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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 Brand and the generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan)
<b>Part B Prerequisite</b>	No

# BOSULIF

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## 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
Age Restrictions	ALL - 15 years and older. Myeloid/lymphoid neoplasms w eosinophilia- 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	CML-approve if the patient has Ph-positive or BCR::ABL1-positive CML. For Ph-positive ALL-approve. Myeloid/lymphoid neoplasms with eosinophilia - approve if tumor has an ABL1 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia, myeloid/lymphoid neoplasms with eosinophilia
Part B Prerequisite	No

# BOTOX

## Products Affected

- BOTOX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Use in the management of cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, rejuvenation of the peri-orbital region)
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Blepharospasm/Strabismus-12 years and older. Pediatric NDO-5 years and older. Limb spasticity-2 years and older. All other dx-18 years and older.
<b>Prescriber Restrictions</b>	Migraine headache prevention-prescribed by, or after consultation with, a neurologist or HA specialist.
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	Blepharospasm-approve, Strabismus-approve, Cervical 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). Urinary incontinence associated with a neurological condition (e.g., spinal cord injury, multiple sclerosis) approve after a trial with at least one other pharmacologic therapy (e.g., anticholinergic medication), Adult Overactive Bladder with symptoms of Urge Urinary Incontinence, Urgency and Frequency-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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<b>Off-Label Uses</b>	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)
<b>Part B Prerequisite</b>	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 and B): A) The patient has BRAF V600E mutation-positive disease AND B) meets (i or ii): i) will be used as first-line systemic therapy for metastatic disease in combination with Erbitux (cetuximab intravenous infusion) and mFOLFOX6 (5-FU, leucovorin, and oxaliplatin) or ii) patient has previously received a chemotherapy regimen for colon or rectal cancer and this 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). Appendiceal adenocarcinoma-approve if (A, B and C): A) BRAF V600E mutation-positive, and B) used as subsequent therapy for advanced or metastatic disease, and C) used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Appendiceal adenocarcinoma
Part B Prerequisite	No

# BRINSUPRI

## Products Affected

- BRINSUPRI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or infectious disease physician (initial and continuation)
Coverage Duration	1 year
Other Criteria	BRONCHIECTASIS, NON-CYSTIC FIBROSIS, INITIAL-all the following (A, B, C and D): A. History of bronchiectasis as diagnosed by chest computed tomography, AND B. ONE of the following (i or ii): i. Greater than or equal to 12 years of age and less than 18 years of age: Patient has had at least one pulmonary exacerbation in the last 12 months that resulted in the prescription of an antibiotic agent, OR ii. Greater than or equal to 18 years of age: Patient has had at least two pulmonary exacerbations in the last 12 months that resulted in the prescription of an antibiotic agent, AND C. Respiratory symptoms are not driven primarily by chronic obstructive pulmonary disease or asthma, AND D. Does not have cystic fibrosis. BRONCHIECTASIS, NON-CYSTIC FIBROSIS, CONTINUATION-all the following (A and B): A. Does not have cystic fibrosis, AND B. Experienced a beneficial clinical response. Note: Examples of beneficial clinical response may include a reduction in the number of exacerbations or preservation of lung function, reduced cough, reduced sputum production, or less shortness of breath.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# BRIUMVI

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## 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

# BRUKINSA

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## Products Affected

- BRUKINSA ORAL CAPSULE
- BRUKINSA ORAL TABLET

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	Follicular Lymphoma - approve if pt tried at least two other systemic regimens and will use this in combination with Gazyva (obinutuzumab intravenous infusion). Mantle Cell Lymphoma/CLL/SLL - approve. Marginal zone lymphoma-approve if the patient has tried at least one systemic regimen. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma-approve. Hairy Cell Leukemia - approve if pt has received therapy for relapsed or refractory disease AND pt has progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Hairy Cell Leukemia
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	<p>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.</p> <p>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 decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.</p> <p>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</p>

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

# BYOOVIZ

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## 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 (Cinryze and Haegarda only), Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50 percent of normal) at baseline and lower than normal serum C4 levels at baseline. Patient is currently taking Cinryze or Haegarda 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 (Berinert and Ruconest only), 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 with Berinert or Ruconest: 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A



PA Criteria	Criteria Details
Part B Prerequisite	No

# CABLIVI

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## 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	Neuroendocrine tumor/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 positive tumor. Neuroendocrine tumors- approve if (A and B): A) pt has locally advanced, unresectable, or metastatic disease, and B) meets (i or ii): i) patient has well-differentiated neuroendocrine tumors, or ii) patient has pancreatic or extra-pancreatic neuroendocrine tumors and the medication will be used as subsequent therapy. Adrenal gland tumor- approve if pt has locoregional unresectable or metastatic adrenocortical carcinoma. Pheochromocytoma/paraganglioma- approve if pt has locally unresectable disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Patients with Non-Small Cell Lung Cancer, Gastrointestinal stromal tumors (GIST), Bone cancer, Endometrial carcinoma, Adrenal gland tumor, Pheochromocytoma/paraganglioma
<b>Part B Prerequisite</b>	No

# CALQUENCE

## Products Affected

- 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 meets (A or B): A) 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) or B) this medication is used in combination with rituximab. 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 Macroglobulinemia/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.
Part B Prerequisite	No

# CAMCEVI

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## Products Affected

- CAMCEVI (6 MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prostate cancer-prescr/consult with oncologist or urologist. For the treatment of other cancer diagnosis must be prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	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	Head and neck cancer-salivary gland tumors
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	<p>Obstructive hypertrophic cardiomyopathy, initial-Approve if the pt meets the following criteria (i, ii and iii): 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]). Cont-Approve if pt meets ALL of the following criteria (i, ii, iii and iv): 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</p>

PA Criteria	Criteria Details
	<p>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.)</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# CAPRELSA

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## 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 oncocytic) 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 than 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

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## 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, infectious diseases specialist or a physician who specializes in the treatment of cystic fibrosis.
Coverage Duration	1 year
Other Criteria	Approve if the patient has <i>Pseudomonas aeruginosa</i> 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

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## 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
<b>Exclusion Criteria</b>	Concomitant use with other approved therapies for Gaucher disease such as Cerdelga (eliglustat capsules), Elelyso (taliglucerase alfa injection), Vpriv (velaglucerase alfa injection), and Zavesca (miglustat capsules).
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results
<b>Age Restrictions</b>	Greater than or equal to 2 years of age
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Gaucher Disease, Type 1 (non-neuronopathic Gaucher disease)-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene. Gaucher Disease, Type 3 (chronic neuronopathic Gaucher disease)-approve if both (A and B): A) there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene, and B) medication is not being used for management of neurological manifestations AND is being used for management of impaired growth, hematologic, or visceral symptoms.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Type 3 Gaucher Disease
<b>Part B Prerequisite</b>	No

# CHEMET

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## 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

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## 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
<b>Exclusion Criteria</b>	Combination therapy with Chenodal
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with hepatologist, metabolic specialist, or GI
<b>Coverage Duration</b>	3 mos initial, 12 mos cont
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CHORIONIC GONADOTROPINS (HCG)

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## 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
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	AD-12 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
<b>Coverage Duration</b>	Initial-Atopic Dermatitis-3 months, Continuation-1 year
<b>Other Criteria</b>	Atopic Dermatitis, initial-approve if the patient has had a 4-month trial of at least one systemic therapy OR patient has tried at least one systemic therapy but was unable to tolerate a 4-month trial. Note: Examples of systemic therapies include Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection). Methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil also count towards a trial of one systemic therapy. Continuation-Approve if the patient has been receiving Cibinqo for at least 90 days AND patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Cibinqo) in at least one of the following: estimated body surface area affected, erythema, induration/papulation/edema, excoriations, lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis AND compared with baseline (prior to receiving Cibinqo), patient experienced an improvement in at least one symptom, such as decreased itching. Note: A patient who has received less than 3 months of therapy or who is restarting therapy with Cibinqo should be considered under initial therapy.
<b>Indications</b>	All FDA-approved Indications.

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

# CIMERLI

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## 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
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried
<b>Age Restrictions</b>	18 years and older for CD and PP (initial therapy). 2 years and older for JIA (initial therapy).
<b>Prescriber Restrictions</b>	All dx initial therapy only. RA, AS, JIA, 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
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	AS initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Xeljanz/XR, Cosentyx. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. PsA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Cosentyx, Tremfya, a preferred ustekinumab product, Otezla, Orencia, Rinvoq, Skyrizi or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab/ustekinumab product will also count. RA initial tx, approve if the patient has tried two of the following drugs in the past: Enbrel, a preferred adalimumab product, 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. CD initial tx, approve if patient has previously tried ONE of the following drugs in the past: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Skyrizi, Rinvoq, or Tremfya. Note: if the patient does not meet this requirement, a previous trial of

PA Criteria	Criteria Details
	<p>another non-preferred adalimumab/infliximab/ustekinumab product will also count. Plaque Psoriasis (PP), initial tx-approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya, Sotyktu. A trial of a non-preferred adalimumab/ustekinumab also counts. JIA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, Orencia, Rinvoq/LQ, Xeljanz, a preferred adalimumab product. Note pt does not meet this requirement, a trial with a non-preferred adalimumab, Simponi Aria, tocilizumab, Kevzara, or infliximab will also count. Cont tx, AS/PsA/RA/CD/PP/JIA - 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. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred infliximab products include Remicade, Zymfentra. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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	<p>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 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.</p>

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

# CLOBAZAM

## Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*
- ONFI ORAL SUSPENSION
- ONFI ORAL TABLET
- SYMPAZAN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other medications tried
<b>Age Restrictions</b>	2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist (initial therapy)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Dravet Syndrome and treatment-refractory seizures/epilepsy
<b>Part B Prerequisite</b>	No

# CLOMIPHENE

## Products Affected

- *clomid*
- *clomiphene citrate*
- *milophene*

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	<p>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 indolent lymphoma. Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and DHA (dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin) +/- rituximab. Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma- approve if the patient has received two or more lines of systemic therapy, the medication will be given as a single agent and the patient has or will receive pretreatment with obinutuzmab intravenous infusion before the first dose of Columvi. Note: HIV-related B-cell lymphomas includes HIV-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus-8 (HHV8) positive DLBCL. Note: 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</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	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 obinutuzumab 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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma.Post-transplant lymphoproliferative disorders.
<b>Part B Prerequisite</b>	No

# COMETRIQ

## Products Affected

- COMETRIQ ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY(80 MG X1-20 MG X1), 140 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	1 year
Other Criteria	MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and oncocyctic) 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 oncocyctic) 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

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## 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
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis and previous medications use
<b>Age Restrictions</b>	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
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: HIDRADENITIS SUPPURATIVA (HS): tried at least one other therapy (e.g. systemic antibiotics, isotretinoin). NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation and meets a or b: a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI. PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of at least one biologic that is not Cosentyx or a Cosentyx biosimilar also counts) or B) contraindication to MTX. CONTINUATION THERAPY: ALL INDICATIONS: patient has experienced benefit from the medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# COSENTYX IV

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## 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	Approve through end of plan year
Other Criteria	Non-Radiographic Axial Spondyloarthritis, initial therapy- approve if pt has objective signs of inflammation defined as (a or b): a) C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or b) sacroiliitis reported on magnetic resonance imaging. For continuation of therapy for all covered indications - approve if the pt has benefit from the medication.
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	Diagnosis
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 AND patient has BRAF V600 mutation positive disease. 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/neuroglioma/glioneuronal tumor OR ii. Recurrent or progressive disease for one of the following conditions (a or b): a) glioma/circumscribed glioma OR b) Glioblastoma, 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Cancer
Part B Prerequisite	No

# CRENESSITY

## Products Affected

- CRENESSITY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	4 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, urologist, or a physician who specializes in the treatment of adrenal hyperplasia (initial)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	INITIAL-CLASSIC CONGENITAL ADRENAL HYPERPLASIA (CAH)-Patient meets BOTH of the following (a and b): a) The medication will be taken in combination with a systemic glucocorticoid, Note: Examples of glucocorticoids include hydrocortisone, prednisone, prednisolone, or dexamethasone, AND b) Patients has a diagnosis of 21-hydroxylase deficiency CAH confirmed by ONE of the following (1, 2, 3, or 4): 1. Elevated 17-hydroxyprogesterone level, OR 2. Confirmed cytochrome (CYP)21A2 genotype, OR 3. Positive newborn screening with confirmatory second-tier testing, OR 4. Diagnostic results after cosyntropin stimulation. CONTINUATION, CAH-patient is continuing to derive benefit.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

## CRESEMBA (ORAL)

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### 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

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## 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
<b>Exclusion Criteria</b>	Chronic Kidney Disease (CKD), Severe Renal Impairment or End Stage Renal Disease
<b>Required Medical Information</b>	Diagnosis, lab values
<b>Age Restrictions</b>	TIO-2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or nephrologist (initial therapy)
<b>Coverage Duration</b>	XLH-1 year (initial/cont), TIO-initial-6 months, cont-1 year
<b>Other Criteria</b>	<p>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 pathogenic variant 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.</p> <p>TIO-approve if the patient has a mesenchymal tumor that cannot be curatively resected or identified/localized AND the patient is currently exhibiting one or more signs or symptoms of TIO AND patient has had a baseline (prior to any TIO treatment) serum phosphorus level that was below the normal range for age AND patient has had a baseline (prior to any TIO treatment) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender. Cont-approve if the patient is continuing to derive benefit as determined by the prescribing physician.</p>
<b>Indications</b>	All FDA-approved Indications.

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

# CTEXTLI

## Products Affected

- CTEXTLI

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Cholbam (cholic acid capsules)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, neurologist, ophthalmologist, metabolic specialist who treats patients with cerebrotendinous xanthomatosis or a specialist who focuses in the treatment of cerebrotendinous xanthomatosis.
Coverage Duration	1 year
Other Criteria	CEREBROTENDINOUS XANTHOMATOSIS- patient has a molecular genetic test demonstrating a pathogenic variant in the cytochrome P450 27A1 (CYP27A1) gene OR laboratory test demonstrating elevated serum cholestanol levels.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# CYSTEAMINE (OPHTHALMIC)

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## 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

# DANZITEN

## Products Affected

- DANZITEN
- NILOTINIB D-TARTRATE ORAL CAPSULE 150 MG, 200 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	ALL - 15 years and older, GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	CML- approve if BCR::ABL1-mutation positive or Philadelphia chromosome positive. ALL-Philadelphia chromosome positive. Pigmented villonodular synovitis/tenosynovial giant cell tumor-patient has tried Turalio or Romvimza or cannot take Turalio or Romvimza. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafenib or ripretinib. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement. For melanoma, cutaneous - approve if the patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute lymphoblastic leukemia, Pigmented villonodular synovitis/Tenosynovial giant cell tumor, GIST, cutaneous melanoma and myeloid/lymphoid neoplasms with eosinophilia
Part B Prerequisite	No

# DATROWAY

## Products Affected

- DATROWAY

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. BREAST CANCER - All of (A, B, C, D and E): A) Unresectable or metastatic disease, AND B) Hormone receptor (HR)-positive disease, AND C) Human epidermal growth factor receptor 2 (HER2)- negative (immunohistochemistry [IHC] 0, IHC 1+, or IHC 2+/in situ hybridization [ISH]-negative) disease, AND D) Patient has received prior endocrine-based therapy, Note: Examples of endocrine therapy are tamoxifen, anastrozole, letrozole, exemestane, AND E) Patient has received prior chemotherapy for unresectable or metastatic disease. Note: Examples are paclitaxel, doxorubicin, liposomal doxorubicin, gemcitabine, capecitabine, vinorelbine, Halaven (eribulin intravenous infusion), cyclophosphamide, docetaxel. Non-Small Cell Lung Cancer- meets ALL (A, B, and C): A) locally advanced or metastatic disease AND B) EGFR-mutated disease AND C) meets BOTH (i and ii): i. tried at least one prior EGFR-directed therapy AND ii. tried platinum-based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No



# DAURISMO

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## 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

# DAWNZERA

## Products Affected

- DAWNZERA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other Hereditary Angioedema (HAE) prophylactic therapies.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	HEREDITARY ANGIOEDEMA (HAE) DUE TO C1 INHIBITOR (C1-INH) DEFICIENCY, PROPHYLAXIS, INITIAL-HAE type I or type II as confirmed by the following diagnostic criteria (A and B): Note: A diagnosis of HAE with normal C1-INH (also known as HAE type III) does NOT satisfy this requirement. A) Low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values, AND B) Lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. HAE DUE TO C1 INHIBITOR (C1-INH) DEFICIENCY, PROPHYLAXIS, CONTINUATION-HAE type I or type II - patient has had a favorable clinical response since initiating Dawnzera prophylactic therapy compared with baseline.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DAYBUE

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## 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 if 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

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## 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

# DIABETIC SUPPLY - ALCOHOL PADS

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## Products Affected

- *alcohol pads*
- DROPSAFE ALCOHOL PREP PADS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# DIABETIC SUPPLY - GAUZE PADS

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## Products Affected

- GAUZE PADS 2 X 2

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No



# DIABETIC SUPPLY - NEEDLES

## Products Affected

- NOVO PEN NEEDLE
- PEN NEEDLES (NON-PREFERRED BRANDS)
- BD PEN NEEDLE
- EMBECTA PEN NEEDLE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body AND either (i or ii): (i) the patient is either requesting a preferred needle, or has tried one of the following preferred needles: Novofine, Novofine Plus, Novotwist, Novofine Autocover, BD Insulin Pen Needle UF Mini, BD Nano Pen Needle, BD Ultra-Fine Pen Needle, BD Autosshield Duo Pen Needle, or Embecta needles or (ii) the prescriber states the patient requires a needle of the requested length and/or gauge which is not available in any of the preferred products.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# DIABETIC SUPPLY - SYRINGES

## Products Affected

- EMBECTA INSULIN SYRINGE
- BD INSULIN SYRINGE
- INSULIN SYRINGES (NON-PREFERRED BRANDS)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body AND either (i or ii): (i) the patient is either requesting a preferred syringe, or has tried one of the following preferred syringes: BD Eclipse, BD Insulin Syringe, BD Safetyglide, BD Safetyglide Syringe, BD Luer-Lok Syringe, Embecta syringes or (ii) the prescriber states the patient requires a needle of the requested length and/or gauge which is not available in any of the preferred products.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# DIACOMIT

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## 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)

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## 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
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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
Age Restrictions	Thrombocytopenia in chronic liver disease - 18 years and older
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 (A and B): A) current platelet count less than 50 x 10 <sup>9</sup> /L and B) scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. CHRONIC ITP, INITIAL THERAPY (A and B): A): (i or ii): i) platelet count less than 30,000 microliters or ii) platelet count less than 50,000 microliters and patient is at an increased risk of bleeding, and B) tried one other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, eltrombopag tablets and oral suspension, romiplostim subcutaneous injection, fostamatinib tablets, rituximab) or had a splenectomy. CHRONIC ITP, CONTINUATION THERAPY: patient had 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

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## 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.
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 200  
MG/1.14 ML, 300 MG/2 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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].
<b>Required Medical Information</b>	Diagnosis, prescriber specialty, other medications tried and length of trials. COPD INITIAL: meets (all of A, B, and C): A) blood eosinophil at least 300 cells per microliter within previous 6 weeks or prior to Dupixent or another monoclonal antibody, and B) received at least 3 months of combination therapy with at least two of LAMA, LABA or ICS, and, and C) meets (i or ii): i) two or more COPD exacerbations in previous 12 months requiring systemic CS or antibiotics or ii) COPD exacerbation requiring hospitalization in previous 12 months. COPD CONTINUATION (all of A, B and C): A) received Dupixent for at least 6 months and B) continues LABA and LAMA, and C) beneficial response (e.g. reduced symptoms, exacerbations, hospitalizations, ED/urgent care visits, improved lung function). CSU INITIAL: urticaria for greater than 6 weeks (prior to Dupixent), with symptoms at least 3 days/week despite daily non-sedating H1 antihistamine tx. CSU CONTINUATION (A and B): A) received at least 6 months of Dupixent and B) experienced a beneficial clinical response, defined by decreased itch severity, decreased number of hives or decreased size of hives. Bullous Pemphigoid Initial: Approve. Bullous Pemphigoid Continuous: meets both (i and ii): i. received at least 6 months of therapy with Dupixent AND ii. experienced a beneficial clinical response, defined by decreased area of skin involvement, lesions, including blisters or erosions (bullae), urticaria, erythema, or reduced or no need for systemic or topical corticosteroid therapy.
<b>Age Restrictions</b>	Initial therapy only: AD-6 months and older, asthma-6 years of age and older, Esophagitis-1 yr and older, Chronic Rhinosinusitis/CSU- 12 and older, Prurigo nodularis/COPD/BP-18 and older
<b>Prescriber Restrictions</b>	Initial therapy only: Atopic Dermatitis/prurigo nodularis/CSU-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

PA Criteria	Criteria Details
	allergist, immunologist or otolaryngologist. Esophagitis-prescr/consult-allergist or gastro. COPD-prescribed by or in consultation with an allergist, immunologist, or pulmonologist. BP-prescr/consult with derm
Coverage Duration	AD-Init-4mo, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/PN/COPD/CSU/BP-init-6 mo, cont 1 yr
Other Criteria	<p>INITIAL CRITERIA: AD: tried at least 1 medium to super-high-potency topical corticosteroid (CS), unless topical CS therapy not advisable or pt is less than 2 years old. ASTHMA (all of A, B, and C): A) blood eosinophil greater than or equal to 150 cells per microliter within previous 6 weeks or within 6 weeks prior to Dupixent or another monoclonal antibody or has oral CS-dependent asthma, B) used an ICS in combination with at least one additional asthma controller/maintenance medication, and C) uncontrolled asthma prior to any asthma monoclonal antibody as defined by one of the following (one of a, b, c, d, or e): a) two or more asthma exacerbations requiring oral CS in the past year, b) one or more asthma exacerbations requiring hospital/urgent care/ED visit in the past year, c) FEV1 less than 80 percent predicted (adults only), d) FEV1/FVC less than 0.8, or e) worsened asthma with oral CS taper. CRSwNP (all of A, B, C and D): A) concurrent use with nasal CS, B) presence of at least two of the following symptoms for 6 months: nasal congestion, nasal obstruction, nasal discharge, reduction/loss of smell, C) received oral CS at least 5 days in last 2 years (unless contraindicated) or patient had prior surgery for nasal polyps, and D) diagnosis confirmed by direct exam, endoscopy, or sinus CT. EoE (all of A, B, C, and D): A) weighs 15 kg or more, B) endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, C) does not have a secondary cause of EoE, and D) received an Rx-strength PPI for at least 8 weeks. PRURIGO NODULARIS: approve if pt has pruritus lasting at least 6 weeks.</p> <p>CONTINUATION CRITERIA: AD: responding positively to therapy. ASTHMA: responding positively to therapy and concurrent use with ICS. CRSwNP (all of A, B, and C): A) received Dupixent for at least 6 months, B) responding positively to therapy, and C) concurrent use with intranasal CS. EoE (A and B): A) received Dupixent for at least 6 months and B) reduction in intraepithelial eosinophil count, decreased dysphagia/pain upon swallowing, or reduced frequency/severity of food impaction. PRURIGO NODULARIS (A and B): A) received Dupixent for at least 6 months and B) reduction in nodular lesion count, pruritis, or nodular lesion size.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# DURYSTA

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## Products Affected

- DURYSTA

PA Criteria	Criteria Details
Exclusion Criteria	Re-treatment of previously treated eyes. Concurrent use with iDose TR (travoprost intracameral implant).
Required Medical Information	Diagnosis
Age Restrictions	18 years or older
Prescriber Restrictions	Administered by or under the supervision of an ophthalmologist
Coverage Duration	Approve one time use for each treated eye (i.e., one implant per treated eye)
Other Criteria	Ocular hypertension or open-angle glaucoma-approve if the patient has previously tried two ophthalmic prostaglandins and experienced inadequate efficacy or adverse events severe enough to warrant discontinuation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# DUVYZAT

## Products Affected

- DUVYZAT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	6 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders (initial/continuation)
Coverage Duration	1 year
Other Criteria	INITIAL THERAPY: DUCHENNE MUSCULAR DYSTROPHY (DMD)-All of (i, ii and iii): i. DMD is confirmed by genetic testing with a confirmed pathogenic variant in the dystrophin gene, AND ii. Patient is ambulatory, AND iii. Patient is on a stable systemic corticosteroid therapy for at least 6 months.CONTINUATION THERAPY: DMD-All of (i and ii): i. Patient is continuing to receive stable systemic corticosteroid therapy, AND ii. Patient continues to benefit from therapy, as demonstrated by a stabilization or slowed decline on timed function tests (e.g., 4-stair climb, 6-minute walk test, time-to-rise) or in the North Star Ambulatory Assessment (NSAA) score.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# DYCLOPRO

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## Products Affected

- DYCLOPRO

PA Criteria	Criteria Details
Exclusion Criteria	Use prior to a procedure (e.g., endoscopic procedure)
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

# DYSPORT

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## Products Affected

- DYSPORT

PA Criteria	Criteria Details
Exclusion Criteria	Use in the management of cosmetic uses.
Required Medical Information	N/A
Age Restrictions	Spasticity-2 years and older. All other dx-18 years and older.
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	Anal fissure, hemifacial spasm, chronic sialorrhea, blepharospasm, oromandibular dystonia
Part B Prerequisite	No



# EBGLYSS

## Products Affected

- EBGLYSS PEN
- EBGLYSS SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another monoclonal antibody therapy. Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical].
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
<b>Coverage Duration</b>	Initial-4 months, Continuation-1 year
<b>Other Criteria</b>	INITIAL, ATOPIC DERMATITIS- All of (A, B, and C): A. 12 to 17 years of age must weigh greater than or equal to 40 kg, and B. Atopic dermatitis involvement estimated to be greater than or equal to 10 percent of the body surface area, and C. Tried at least one medium to super-high-potency prescription topical corticosteroid. CONTINUATION, ATOPIC DERMATITIS-patient has received at least 4 months of therapy with Ebglyss and has responded to therapy. Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Ebglyss should be considered under initial therapy. In addition, patients new to therapy are required to try Dupixent prior to approval of Ebglyss.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# EGRIFTA

## Products Affected

- EGRIFTA SV
- EGRIFTA WR

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

# EKTERLY

## Products Affected

- EKTERLY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an allergist/immunologist or a physician who 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 - TREATMENT OF ACUTE ATTACKS-HAE type I or type II as confirmed by the following diagnostic criteria (a and b): Note: A diagnosis of HAE with normal C1-INH (also known as HAE type III) does NOT satisfy this requirement. a) Low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values, AND b) Lower than normal serum C4 levels at baseline, as defined by the laboratory reference values.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ELAHERE

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## Products Affected

- ELAHERE

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. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer-approve if the patient meets (A and B): A) Patient has folate receptor alpha positive disease and either (1 or 2): 1) greater than or equal to 75% folate receptor alpha positive tumor cells or 2) patient is using this medication in combination with bevacizumab, AND B) Patient has platinum-resistant disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ELAPRASE

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

# ELELYSO

## Products Affected

- ELELYSO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other approved therapies for Gaucher disease such as Cerdelga (eliglustat capsules), Cerezyme (imiglucerase injection), Vpriv (velaglucerase alfa injection), and Zavesca (miglustat capsules).
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results
<b>Age Restrictions</b>	4 years and older
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Gaucher Disease, Type 1 (non-neuronopathic Gaucher disease)-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene. Gaucher Disease, Type 3 (chronic neuronopathic Gaucher disease)-approve if both (A and B): A) there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene, and B) medication is not being used for management of neurological manifestations AND is being used for management of impaired growth, hematologic, or visceral symptoms.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Type 3 Gaucher Disease
<b>Part B Prerequisite</b>	No

# ELFABRIO

## Products Affected

- ELFABRIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with Galafold (migalastat oral capsules). Concurrent Use with Fabrazyme (agalsidase beta intravenous infusion).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 a pathogenic variant in the galactosidase alpha (GLA) gene.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ELREXFIO

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## 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

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## 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

# EMFLAZA

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## Products Affected

- *deflazacort*
- EMFLAZA
- *jaythari*
- *pyquvi*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prescriber specialty
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	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)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial therapy-approve if the patient's diagnosis is confirmed by genetic testing with a confirmed 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# EMGALITY

## Products Affected

- EMGALITY PEN MG/ML, 300 MG/3 ML (100 MG/ML X 3)
- EMGALITY SYRINGE
- SUBCUTANEOUS SYRINGE 120

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination therapy with another cGRP inhibitor for migraine headache prevention
<b>Required Medical Information</b>	Diagnosis, number of migraine or cluster headaches per month
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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) If pt is currently taking Emgality, pt has had significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Emgality was initiated. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# EMPAVELI

## Products Affected

- EMPAVELI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Soliris for greater than 4 weeks. Concurrent use with Fabhalta or Ultomiris or Voydeya
<b>Required Medical Information</b>	Diagnosis, test results
<b>Age Restrictions</b>	PNH-18 years and older (initial therapy and continuation). C3G and IC-MPGN - 12 years and older (initial and continuation).
<b>Prescriber Restrictions</b>	PNH-prescribed by or in consultation with a hematologist (initial therapy and continuation). C3G and IC-MPGN - prescribed by or in consultation with a nephrologist (initial and continuation).
<b>Coverage Duration</b>	All diagnoses-initial 6 months, cont-1 year
<b>Other Criteria</b>	<p>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. Complement 3 Glomerulopathy (C3G) and Immune-Complex Membranoproliferative Glomerulonephritis, Primary (IC-MPGN)-INITIAL (A, B and C): A) diagnosis confirmed by biopsy, and B) pt has urine protein-to-creatinine ratio greater than or equal to 1.0g/g, and C) pt has recieved maximum or maximally tolerated dose of ACE inhibitor, ARB or SGLT2 inhibitor for greater than or equal to 12 weeks prior to starting Empaveli. PNH 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, improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score). C3G/IC-MPGN-CONTINUATION (A and B): A) diagnosis confirmed by biopsy, and B) pt has had a response to Empaveli.</p>
<b>Indications</b>	All FDA-approved Indications.

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

# EMRELIS

## Products Affected

- EMRELIS

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. NON-SMALL CELL LUNG CANCER- ALL of the following (A, B and C): A. Patient has locally advanced or metastatic, non-squamous disease, AND B. Tumor has high c-Met protein overexpression, defined as a greater than or equal to 50 percent of tumor cells with strong [3+] staining, as determined by an approved test, AND C. Patient has received at least one prior systemic therapy. Note: Examples are cisplatin, carboplatin, pemetrexed, Keytruda (pembrolizumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Imfinzi (durvalumab intravenous infusion), Libtayo (cemiplimab-rwlc intravenous infusion)
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
<b>Exclusion Criteria</b>	Concurrent use with biologic therapy or targeted synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	PP-4 years and older (initial therapy)
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA): tried one conventional synthetic DMARD for at least 3 months (see Note 1). JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA (one of A, B, C, or D): A) patient has aggressive disease, B) tried one other systemic therapy (e.g., methotrexate [MTX], sulfasalazine, leflunomide, NSAID, or a biologic that is not a biosimilar of the requested product), C) patient will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide, or D) patient has an absolute contraindication to MTX, sulfasalazine, or leflunomide. PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent for at least 3 months, unless intolerant (e.g., MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA) [see Note 1] or B) patient has a contraindication to one oral agent for psoriasis such as MTX. GRAFT VERSUS HOST DISEASE (GVHD): approve. BEHCET'S: tried at least one conventional therapy (e.g., systemic corticosteroid, immunosuppressant, interferon alfa, mycophenolate), adalimumab, or

<b>PA Criteria</b>	<b>Criteria Details</b>
	infliximab. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Note 1: a biologic that is not a biosimilar of the requested product will also count.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Graft versus host disease (GVHD), Behcet's disease
<b>Part B Prerequisite</b>	No



# ENDARI

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## Products Affected

- ENDARI
- *glutamine (sickle cell)*

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	<p>Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. BREAST CANCER (HER2-positive): meets all of (A, B and C): A) recurrent or metastatic breast cancer, and B) HER2-positive disease (immunohistochemistry [IHC] 3+ or in situ hybridization [ISH] positive), and C) one of (1 or 2): 1) tried at least one other regimen or 2) had disease recurrence during or within 6 months of completing neoadjuvant or adjuvant therapy (within 12 months for Perjeta [pertuzumab injection]-containing regimens) and the medication is used as first-line therapy. BREAST CANCER (HR-Positive, HER2-Low or Ultra-Low): meets all of (A, B, C and D): A) recurrent, unresectable, or metastatic disease, and B) hormone receptor (HR)-positive disease with visceral crisis or is refractory to endocrine therapy, and C) HER2-low or HER2-ultra-low (IHC 0+, 1+, 2+ or ISH negative), and D) meets (i or ii): i) will be used as first-line therapy and is negative for germline BRCA 1/2 mutation and patient has tried at least one line of endocrine-based therapy in the metastatic setting, or ii) will be used as second-line therapy.</p> <p>BREAST CANCER (HR-Negative, HER2-Low or Ultra-Low): meets all of (A, B, C, D and E): A) recurrent, unresectable, or metastatic disease, and B) HR-negative disease, and C) negative for germline BRCA 1/2 mutation, and D) HER2-low or HER2-ultra-low (IHC 0+, 1+, 2+ or ISH negative), and E) meets (i or ii): i) used as first-line therapy after the disease has progressed during or within 6 months after completing adjuvant</p>

PA Criteria	Criteria Details
	<p>chemotherapy, or ii) used in the subsequent therapy setting (second- or later-line). GASTRIC or GASTROESOPHAGEAL JUNCTION CANCER: meets (A and B): A) HER2-positive disease (IHC 3+ or IHC 2+/ISH positive) and B) received at least one prior trastuzumab-based regimen. NON-SMALL CELL LUNG CANCER: meets (A, B and C): A) unresectable or metastatic disease, and B) activating HER2 mutations, and C) tried at least one prior systemic therapy. SOLID TUMORS (examples: bladder cancer, biliary tract cancer, cervical cancer, colorectal cancer, endometrial cancer, ovarian cancer, pancreatic cancer, salivary gland tumors) meets (A, B, C and D): A) unresectable or metastatic disease, and B) HER2-positive disease (IHC 3+), and C) received prior systemic treatment, and D) there are no satisfactory alternative treatment options.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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	<p>Cold Agglutinin Disease-approve if the patient meets the following criteria:</p> <p>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 causes of cold agglutinin syndrome include infection, rheumatologic diseases, and active hematologic malignancies.</p>
Indications	All FDA-approved Indications.

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

# ENSPRYNG

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## Products Affected

- ENSPRYNG

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Soliris, rituximab, Ultomiris 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. 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

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## 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

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## Products Affected

- ENTYVIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with Other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) used for an Inflammatory Condition
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	CD/UC - adults (initial therapy)
<b>Prescriber Restrictions</b>	CD/UC initial - Prescribed by or in consultation with a gastroenterologist. (initial therapy)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	CD Initial - approve. Cont tx - had a response to Entyvio, as determined by the prescribing physician. UC initial- approve. Cont tx - had a response to Entyvio (for example, decreased stool frequency or rectal bleeding), as determined by the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# ENTYVIO PEN

## Products Affected

- ENTYVIO PEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs) used for an inflammatory condition.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist (initial)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	<p>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: a preferred ustekinumab product, Entyvio IV, Skyrizi, Tremfya, Rinvoq, a preferred infliximab product, or a preferred adalimumab product. Trials of Omvoh IV/SC, a Non-Preferred infliximab product, Simponi SC, a non-preferred ustekinumab or a Non-Preferred adalimumab product will also count. 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. Crohn's Disease, 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: a preferred adalimumab product, a preferred infliximab, Entyvio IV, a preferred ustekinumab product, Skyrizi, Tremfya or Rinvoq. Trials of a Non-Preferred infliximab product, a non-preferred ustekinumab or a Non-Preferred adalimumab product will also count. OR (ii) the patient has</p>

PA Criteria	Criteria Details
	<p>already started on Entyvio IV or is currently undergoing induction therapy with Entyvio IV. Crohn's disease, continuation of therapy with Entyvio SC: approve if the patient has had a response to therapy. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred infliximab products include Remicade, Zymfentra. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# EOHILIA

## Products Affected

- EOHILIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	11 years and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist or gastroenterologist
Coverage Duration	Not currently on tx - 12 weeks. Pt currently on tx, up to 12 week total for current tx course.
Other Criteria	Eosinophilic esophagitis-Approve if the patient meets the following (A, B and C): (A) Patient has a diagnosis of eosinophilic esophagitis as confirmed by an endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, AND (B) Patient meets ONE of the following (i or ii): (i) Patient has received at least 8 weeks of therapy with a proton pump inhibitor, or (ii) Patient has severe disease with esophageal stricture, AND (C) Patients meets ONE of the following (i or ii): (i) Patient is currently receiving a course of Eohilia and additional medication is needed to complete a 12-week course of treatment, OR (ii) Patient meets ONE of the following (a or b): (a) Patient has not been treated with Eohilia within the previous 6 months, OR (b) Patient is experiencing recurrent worsening dysphagia after discontinuing Eohilia therapy.
Indications	All FDA-approved Indications.
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
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	3 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
<b>Coverage Duration</b>	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1, 2, 3, 4, 5, or 6 must try TWO of the following: velpatasvir/sofosbuvir, Mavyret, Vosevi, unless velpatasvir/sofosbuvir, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype unknown/undetermined must have a trial of velpatasvir/sofosbuvir AND Mavyret prior to approval of Epclusa unless velpatasvir/sofosbuvir and Mavyret are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance
<b>Part B Prerequisite</b>	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 antiseizure drugs or if the patient has tried or is concomitantly receiving one of Diacomit or clobazam or Fintepla. Lennox Gastaut Syndrome-approve if the patient has tried or is concomitantly receiving at least two other 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 one or more lines of systemic therapy. Classic follicular lymphoma - approve if pt has received two or more lines of systemic therapy and medication will be given as a single agent. Human immunodeficiency virus (HIV)-Related B-Cell Lymphoma - approve if the patient has received one or more lines of systemic therapy. 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 one or more lines of systemic therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Human immunodeficiency virus (HIV)-Related B-Cell Lymphoma. Post-transplant lymphoproliferative disorders.
Part B Prerequisite	No

# EPOETIN ALFA

## Products Affected

- 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	Diagnosis
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	Anemia in a pt with Chronic Kidney Disease (CKD) not on dialysis- for initial therapy, approve if hemoglobin (Hb) is less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children, or for continuation of therapy in a pt currently on an erythropoiesis-stimulating agent (ESA) approve if Hb is less than or equal to 12 g/dL. Anemia in a pt with cancer due to chemotherapy- approve if pt is currently receiving myelosuppressive chemo as a non-curative treatment and (for initial therapy) Hb is less than 10.0 g/dL or (if currently on ESA) Hb is less than or equal to 12.0 g/dL. Anemia in HIV with zidovudine- for initial therapy, approve if Hb is less than 10.0 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA, approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Approve if Hb is less than or equal to 13, AND surgery is elective, nonvascular and non-cardiac AND pt is unwilling or unable to donate autologous blood prior to surgery. MDS- for initial therapy, approve if Hb is less than 10 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA approve if Hb is 12.0 g/dL or less. Myelofibrosis- for Initial therapy approve if patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 mU/mL, or for continuation of therapy in pt currently on ESA hemoglobin is less than or equal to 12g/dL. For all covered uses, if the request is for Epogen, then the

<b>PA Criteria</b>	<b>Criteria Details</b>
	patient is required to try Procrit or Retacrit. Anemia in patients with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anemia due to myelodysplastic syndrome (MDS), myelofibrosis
<b>Part B Prerequisite</b>	No



# ERIVEDGE

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## Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	BCC (La or Met) - must not have had disease progression while on Odomzo.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Basal cell carcinoma, locally advanced-approve. 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. Diffuse Basal Cell Carcinoma Formation, including basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma - approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Central nervous System Cancer, diffuse basal cell carcinoma formation
<b>Part B Prerequisite</b>	No

# ERLEADA

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## 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) analog [for example: 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 subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ERLOTINIB

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Advanced or Metastatic NSCLC, approve if the patient has EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of 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.
Part B Prerequisite	No

# EVEKEO

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## Products Affected

- *amphetamine sulfate*
- EVEKEO

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
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis (e.g., oral or IV bisphosphonates, Prolia, Forteo, Tymlos, calcitonin nasal spray) except calcium and Vitamin D
<b>Required Medical Information</b>	Diagnosis, medications that have been tried in the past, other medications that will be used in combination
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months of therapy per course of treatment.
<b>Other Criteria</b>	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 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 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),

<b>PA Criteria</b>	<b>Criteria Details</b>
	chronic kidney disease or has had an osteoporotic fracture or a fragility fracture.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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*
- *torpenz*

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	<p>Breast Cancer-pt meets the following (A,B,C,D,E, and F):A)recurrent or metastatic,HR+ disease AND B)HER2-negative breast cancer AND C)tried at least 1 prior endocrine therapy AND D)meets 1 of the following conditions (i or ii):i.postmenopausal woman or man OR ii.pre/perimenopausal woman AND receiving ovarian suppression/ablation with GnRH agonist, or had surgical bilateral oophorectomy or ovarian irradiation AND E)meets 1 of the following conditions (i or ii): i.Everolimus used in combo w/exemestane and meets 1 of the following:male and receiving a GnRH analog or woman or ii.Everolimus will be used in combo with fulvestrant or tamoxifen AND F)has not had disease progression while on everolimus.RCC, relapsed or Stage IV disease-approve if using for non-clear cell disease or if using for clear cell disease, has tried 1 prior systemic therapy(e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).TSC Associated SEGA-requires therapeutic intervention but cannot be curatively resected.Thymomas and Thymic Carcinomas-has tried chemo or cannot tolerate chemo.TSC associated renal angiomyolipoma-approve.WM/LPL-has progressive or relapsed disease or if has not responded to primary therapy.Thyroid Carcinoma, differentiated-refractory to radioactive iodine therapy.Endometrial</p>

PA Criteria	Criteria Details
	<p>Carcinoma- Everolimus will be used in combo with letrozole. GIST-has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock or imatinib AND there is confirmation that everolimus 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-has perivascular epithelioid cell tumors (PEComa) or recurrent angiomyolipoma/lymphangiomyomatosis. Classic Hodgkin lymphoma-has relapsed or refractory disease AND has tried at least three prior lines of chemotherapy. Histiocytic neoplasm-has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis. Pt must also have PIK3CA mutation. Meningioma-has recurrent or progressive disease AND has surgically inaccessible disease and radiation therapy is not possible AND medication will be used in combination with a somatostatin analogue. Uterine Sarcoma-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. 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) between Brand and generic product which would result in a significant allergy or serious adverse reaction.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	<p>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, meningioma</p>
<b>Part B Prerequisite</b>	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	N/A
Coverage Duration	12 months
Other Criteria	<p>HYPERLIPIDEMIA WITH HoFH (all of A, B, and C): A) meets (a or b): a) phenotypic confirmation (Note 1) of HoFH, or b) meets (i and ii): i) untreated LDL-C greater than 400 mg/dL or treated LDL-C greater than or equal to 300 mg/dL, and ii) clinical manifestations of HoFH before 10 years of age or at least one parent with untreated LDL-C or total cholesterol consistent with FH, AND B) meets (a, b or c): a) tried a PCSK9 inhibitor for at least 8 weeks and LDL-C remains 70 mg/dL or higher, or b) has two LDL-receptor negative alleles, or c) patient is 5 to 9 years of age AND C) meets (a or b): a) tried one high-intensity statin and ezetimibe and LDL-C remains 70 mg/dL or higher or b) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.</p>
Indications	All FDA-approved Indications.

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

# EVRYSDI

## Products Affected

- EVRYSDI ORAL RECON SOLN
- EVRYSDI ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnant patients, female patients not utilizing effective contraception during treatment and for 1 month after the last dose of Evrysdi
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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 muscular atrophy Types 1, 2, or 3. 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</p>

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

# EXONDYS 51

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## 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

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## 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

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## 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

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## 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	PNH: Prescribed by or in consultation with a hematologist (initial/continuation), IgAN/C3G: prescribed by or in consultation with a nephrologist (initial/continuation)
Coverage Duration	Initial-PNH/C3G: 6 months, IgAN: 9 months. continuation- all dx: 1 year
Other Criteria	<p>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. PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN)-INITIAL (A and B): A) diagnosis confirmed by biopsy, and B) high risk of disease progression defined by (i and ii): i) proteinuria greater than 0.5 g/ day or urine protein-to-creatinine ratio greater than or equal to 1.5g/g and ii) received max or max tolerated dose of ACE inhibitor or ARB for at least 12 weeks. COMPLEMENT 3 GLOMERULOPATHY (C3G)-INITIAL (A, B and C): A) diagnosis confirmed by biopsy, and B) pt has urine protein-to-creatinine ratio greater than or equal to 1.0g/g, and C) pt has recieved maximum or maximally tolerated dose of ACE inhibitor or ARB for greater than or equal to 90 days prior to starting Fabhalta.</p> <p>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, improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score. IgAN-CONTINUATION (A and B): A) diagnosis confirmed by biopsy, and B) patient had a</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	response to Fabhalta. C3G-CONTINUATION (A and B): A) diagnosis confirmed by biopsy, and B) pt has had a response to Fabhalta.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FABRAZYME

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## Products Affected

- FABRAZYME

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Galafold (migalastat oral capsules) or Elfabrio (pegunigalsidase alfa intravenous infusion).
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 a pathogenic variant in the galactosidase alpha (GLA) gene.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FASENRA

## Products Affected

- FASENRA PEN
- FASENRA SUBCUTANEOUS  
SYRINGE 10 MG/0.5 ML, 30 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another monoclonal antibody therapy.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Asthma: 6 years of age and older, EGPA: 18 years and older
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	Asthma: 6 months initial, 12 months continuation. EGPA: 8 months initial, 12 months continuation.
<b>Other Criteria</b>	<p>INITIAL THERAPY: ASTHMA (all of A, B, and C): A) blood eosinophil greater than or equal to 150 cells per microliter within previous 6 weeks or within 6 weeks prior to Fasenra or another monoclonal antibody, B) used an inhaled corticosteroid (ICS) in combination with at least one additional asthma controller/maintenance medication, and C) uncontrolled asthma prior to any asthma monoclonal antibody as defined by one of the following (a, b, c, d, or e): a) one or more exacerbations requiring a systemic CS in the past year, b) one or more exacerbations requiring hospital/urgent care/emergency department visit in the past year, c) FEV1 less than 80 percent predicted or less than 90 percent predicted for patients less than 18, d) FEV1/FVC less than 0.80, or e) worsened asthma with systemic CS taper. EGPA: (all of A, B, and C): A) active disease, and B) currently on systemic CS for at least 4 weeks, and C) blood eosinophil greater than or equal to 150 cells per microliter within previous 4 weeks or prior to treatment with any monoclonal antibody that may alter eosinophil levels. CONTINUATION THERAPY: ASTHMA (A and B): A) patient has responded to therapy (e.g., decrease in any of the following: asthma exacerbations, asthma symptoms, hospitalizations, emergency department/urgent care visits, physician visits, requirement for oral corticosteroid therapy) and B) continues to receive therapy with an ICS.</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	EGPA: patient has responded to therapy (e.g. reduced rate of relapse, CS dose reduction, reduced eosinophil levels).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FILSPARI

## Products Affected

- FILSPARI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with any renin-angiotensin-aldosterone antagonists (e.g., angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists, or aliskiren
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial/continuation)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist (initial/continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 m <sup>2</sup> AND patient is at high risk of disease progression, defined by meeting the following criteria (a and b): a) Proteinuria greater than or equal to 0.5 g/day or urine protein-to-creatinine ratio greater than or equal to 0.8 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 m <sup>2</sup> .
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FILSUVEZ

## Products Affected

- FILSUVEZ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with Vyjuvek (beremagene geperpavec-svdt topical gel).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	6 months and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with dermatologist or wound care specialist (initial/continuation).
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	Dystrophic epidermolysis bullosa (DEB)/Junctional epidermolysis bullosa (JEB), initial therapy-approve if the patient meets ALL of the following (a, b, and c): a. Patient has at least one clinical feature of epidermolysis bullosa, AND b. Patient has one or more open wound(s) that will be treated (i.e., target wound[s]), AND c. Target wound(s) meet the following, according to the prescriber [(1), (2), (3), and (4)]: 1. Target wound(s) is clean in appearance and does not appear to be infected, AND 2. Target wound(s) is 10 cm <sup>2</sup> to 50 cm <sup>2</sup> , AND 3. Target wound(s) is greater than or equal to 21 days and less than 9 months old, AND 4. Squamous cell and/or basal cell carcinoma has been ruled out for the target wound(s). Dystrophic epidermolysis bullosa (DEB)/Junctional epidermolysis bullosa (JEB), continuation-approve if the patient meets ALL of the following (i and ii): i. The target wound(s) remains open, AND ii. The target wound(s) has decreased in size from baseline.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FINGOLIMOD

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## Products Affected

- *fingolimod*
- GILENYA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of fingolimod with other disease-modifying agents used for multiple sclerosis (MS).
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
<b>Age Restrictions</b>	10 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist or an MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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

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## 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

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## 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

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## 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.
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-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 meets one of the following: 1) 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), 2) 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 3) patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No

# FYARRO

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## 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-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 meets one of the following: 1) 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), 2) 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 3) 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 Fulphila and Nyvepria and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Fylnetra.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.



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

# GALAFOLD

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## Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Elfabrio (pegunigalsidase alfa intravenous infusion)
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
Age Restrictions	N/A
Prescriber Restrictions	Primary HLH: Prescribed by or in consultation with a hematologist, oncologist, immunologist, transplant specialist, or physician who specializes in hemophagocytic lymphohistiocytosis or related disorders. HLH/MAS: Prescribed by or in consultation with a hematologist, oncologist, immunologist, rheumatologist, or physician who specializes in hemophagocytic lymphohistiocytosis or related disorders.
Coverage Duration	Primary HLH: 6 months, HLH/MAS: 8 weeks
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 degrees C, 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 10 <sup>9</sup> /L OR 3) Neutrophils less than 1.0 x 10 <sup>9</sup> /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. Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS): approve if pt meets (A and B): A) confirmed or suspected diagnosis of systemic juvenile idiopathic arthritis or Still's

<b>PA Criteria</b>	<b>Criteria Details</b>
	disease, adult onset and B) prior to treatment ferritin level greater than 684 ng/mL and at least TWO of the following diagnostic criteria at baseline (TWO of i, ii, iii or iv): i) platelets less than $181 \times 10^9/L$ , ii) AST greater than 48 U/L, iii) fasting triglyceride greater than 156 mg/dL, or iv) fibrinogen less than 360 mg/dL.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# GATTEX

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## 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 advanced, recurrent, or metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Differentiated Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has RET fusion-positive or RET-mutation-positive disease AND disease requires treatment with systemic therapy AND the disease is radioactive iodine-refractory. Anaplastic thyroid cancer or Medullary Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has RET fusion-positive or RET-mutation-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Medullary Thyroid Cancer, Anaplastic Thyroid Cancer
Part B Prerequisite	No

# GEFITINIB

## 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, Some Medically-accepted Indications.
Off-Label Uses	NSCLC with EGFR L861Q, G719X, or S768I mutations.
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	Yes



# GIVLAARI

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

# GLUCAGON-LIKE PEPTIDE-1 AGONISTS

## Products Affected

- BYDUREON BCISE MG/3 ML), 1 MG/DOSE (4 MG/3 ML), 2
- *exenatide subcutaneous pen injector 10* MG/DOSE (8 MG/3 ML)
- *mcg/dose(250 mcg/ml) 2.4 ml, 5 mcg/dose* • RYBELSUS
- *(250 mcg/ml) 1.2 ml* • TRULICITY
- *liraglutide* • VICTOZA 2-PAK
- MOUNJARO • VICTOZA 3-PAK
- OZEMPIC SUBCUTANEOUS PEN
- INJECTOR 0.25 MG OR 0.5 MG (2

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	If the patient is requesting Victoza, approve if the patient has tried two of the preferred products first: Trulicity, Ozempic, Rybelsus, Mounjaro, exenatide. Note: A trial of Ozempic and Rybelsus counts as one preferred product. Approve Victoza if the patient is less than 18 years of age and has tried Trulicity.
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/Head and Neck/Ovarian/Uterine-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, Endometriosis-6 months, 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. 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. Head and Neck Cancer - Salivary Gland Tumors: approve if patient has recurrent, unresectable, or metastatic disease AND has androgen receptor-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Zoladex 3.6mg only: head and neck cancer - salivary gland tumors, Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer, and Uterine Cancer
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.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# GOMEKLI

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## Products Affected

- GOMEKLI ORAL CAPSULE 1 MG, 2 MG
- GOMEKLI ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NEUROFIBROMATOSIS TYPE 1- patient has or had symptomatic plexiform neurofibromas prior to starting Gomekli and the tumor is not amenable to complete resection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# GONADOTROPIN-RELEASING HORMONE AGONISTS - CPP

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## Products Affected

- FENSOLVI
- LUPRON DEPOT-PED
- LUPRON DEPOT-PED (3 MONTH)
- TRIPTODUR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Gender dysphoria- prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender persons
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	gender-dysphoric/gender-incongruent persons, persons undergoing gender reassignment (female-to-male or male-to-female)
Part B Prerequisite	No



# GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

## Products Affected

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)
- LEUPROLIDE ACETATE (3 MONTH)
- *leuprolide subcutaneous kit*
- LUTRATE DEPOT (3 MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prostate cancer- prescribed by or in consultation with an oncologist or urologist. Head and neck-salivary gland tumors- prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	Prostate cancer - for patients new to therapy requesting a non-preferred product (i.e., Leuprolide Depot, Lutrate), approve if the pt has tried a preferred product first: Eligard or Orgovyx. Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Head and neck cancer- salivary gland tumors (Eligard only)
Part B Prerequisite	No

# GRALISE/HORIZANT/LYRICA CR

## Products Affected

- *gabapentin oral tablet extended release 24 hr 300 mg, 450 mg, 600 mg, 750 mg, 900 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 SUBCUTANEOUS SOLUTION 300 MCG/ML
- GRANIX SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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) 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, Leukine) and a reduced dose or frequency of chemotherapy may compromise treatment, OR 4) has received chemotherapy has febrile neutropenia and has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the prescribing physician (e.g., sepsis syndrome, older than 65 years, severe neutropenia - ANC less than 100 cells/mm <sup>3</sup> , neutropenia expected to be

<b>PA Criteria</b>	<b>Criteria Details</b>
	more than 10 days in duration, invasive fungal infection, other clinically documented infections, or prior episode of febrile neutropenia). Patients are required to try Releuko and Nivestym and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Granix unless patient has initiated therapy with Granix and requires additional medication to complete the current cycle of chemotherapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients undergoing peripheral blood progenitor cell (PBPC) Collection and Therapy. Myelodysplastic syndromes.
<b>Part B Prerequisite</b>	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	<p>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 less than 10ng/mL OR had at least 1 GH test less than 10ng/mL 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 less than 10ng/mL 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 less than 10ng/mL 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 or pt has had one GH test less than 10ng/mL 5.pt had a hypophysectomy. Cont-pt responding to therapy</p>
Age Restrictions	ISS 5 y/o or older, SGA 2 y/o or older, SBS and HIV wasting/cachexia 18 y/o or older

PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	ISS - 6 mos initial, 12 months cont tx, SBS-1 month, HIV-48 weeks, others 12 mos
<b>Other Criteria</b>	<p>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, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or SAH, AND 3. meets one of the following - A.has known perinatal insults or congenital or genetic defects or structural hypothalamic 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 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 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</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Short bowel syndrome (all products except Serostim)
<b>Part B Prerequisite</b>	No

# GROWTH HORMONES - LONG-ACTING

## Products Affected

- NGENLA
- SKYTROFA
- SOGROYA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Ngenla- 3 years of age to less than 18 years. Skytrofa- greater than or equal to 1 year of age. Sogroya- greater than or equal to 2.5 years of age
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist (all dx except hypophysectomy)
Coverage Duration	1 year
Other Criteria	<p>GHD child/adol,init-1 of(i,ii,iii,iv,or,v):i.Either(1or2):1-2 stim tests w/levodopa,insulin-induced hypoglyc, arginine, clonidine, or glucagon w/BOTH resp below 10ng/mL OR 2-BOTH (a and b):a-1 stim test below 10ng/mL AND b-at least 1 GHD risk factor ii.Brain radiation/tumor resection AND (1or2):1-1 stim test below 10ng/mL OR 2-1 other pit horm defic (ACTH,TSH,gonadotrop[LH, FSH are 1],prolactin), OR iii.congenital hypopit AND 1 of (1,2or3):1-1 stim test resp below 10ng/mL OR 2-1 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 2-1 stim test below 10ng/mL lab norm. v.Hypophysectomy. GHD child/adol, cont-pt respond to tx. GHD Adult/TransitionAdol (Sogroya/Skytrofa)-ALL of (A,B,C,andD):A)endo certify not for anti-aging/athletic/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)1 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 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</p>



PA Criteria	Criteria Details
	<p>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-Macrilan 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: Macrilan peak less than 2.8ng/mL meets neg resp to stim. 1-Pt off GH tx for at least month before retest AND 2-1 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 (initial and cont)-try Omnitrope with 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).</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HARLIKU

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## Products Affected

- HARLIKU

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant therapy with nitisinone products
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	1 year
Other Criteria	ALKAPTONURIA-one of the following (a or b): a.Genetic testing confirms biallelic pathogenic or likely pathogenic variants in the homogentisate 1,2 dioxygenase (HGD) gene, OR b. Elevated levels of homogentisic acid (HGA) in the urine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# HARVONI

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## 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
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	3 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
<b>Coverage Duration</b>	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1, 4, 5, or 6 must try TWO of the following: ledipasvir/sofosbuvir, Mavyret, Vosevi, unless ledipasvir/sofosbuvir, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance
<b>Part B Prerequisite</b>	No

# HERNEXEOS

## Products Affected

- HERNEXEOS

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-all the following (A, B, C, and D): A) Unresectable or metastatic disease, AND B) Human epidermal growth factor receptor 2 (HER2) [ERBB2] activating mutation, AND C) Mutation was detected by an approved test, AND D) Received at least one prior systemic therapy. Note: Examples include checkpoint inhibitors such as Keytruda (pembrolizumab intravenous infusion), Libtayo (cemiplimab-rwlc intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), or Imjudo (tremelimumab-actl intravenous infusion) in combination with chemotherapy (e.g., carboplatin, cisplatin, pemetrexed, paclitaxel, albumin-bound paclitaxel, bevacizumab), chemotherapy alone (e.g., docetaxel, gemcitabine, etoposide, vinorelbine, other chemotherapy noted above).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# HETLIOZ

## Products Affected

- HETLIOZ
- HETLIOZ LQ
- *tasimelteon*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-24-patient is totally blind with no perception of light
<b>Age Restrictions</b>	Non-24-18 years or older (initial and continuation), SMS-3 years and older
<b>Prescriber Restrictions</b>	prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders (initial and continuation)
<b>Coverage Duration</b>	6 mos initial, 12 mos cont
<b>Other Criteria</b>	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 tasimelteon 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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*
- *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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# HIGH RISK MEDICATIONS - BENZTROPINE

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## 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

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

# HIGH RISK MEDICATIONS - PHENOBARBITAL

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## 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

- *abigale*
- *abigale lo*
- ACTIVELLA
- 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
- *estradiol oral*
- *estradiol transdermal gel in metered-dose pump*
- *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*
- 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
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, Imvexxy or estradiol valerate. For prophylaxis of Postmenopausal Osteoporosis, approve if the

<b>PA Criteria</b>	<b>Criteria Details</b>
	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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	<p>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, 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.</p> <p>Continuation-approve if the patient meets the following criteria (i. and ii.): i. Patient has a definitive diagnosis of tuberous sclerosis complex by</p>

PA Criteria	Criteria Details
	<p>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.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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. 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



PA Criteria	Criteria Details
Part B Prerequisite	No

# IBS - NHE3 INHIBITOR

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## Products Affected

- IBSRELA

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

# IBTROZI

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## Products Affected

- IBTROZI

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-locally advanced or metastatic disease and ROS1-positive non-small cell lung cancer as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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
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	All indications except ALL - 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Acute lymphoblastic leukemia, Philadelphia chromosome positive or ABL-class translocation-approve. Chronic myeloid leukemia-approve. GIST - approve if the patient tried all of the following 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

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## 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
<b>Exclusion Criteria</b>	When used in combination with concurrent biologic therapy (e.g.TNF antagonists, etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or rilonacept.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	CAPS-4 years of age and older (initial). SJIA/HIDS/MKD/FMF/TRAPS-2 years of age and older (initial). Still's disease-18 years and older (initial) Note-patients less than 18 should be referred to criteria for systemic juvenile idiopathic arthritis. Acute gout flare-18 years of age and older
<b>Prescriber Restrictions</b>	CAPS 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.
<b>Coverage Duration</b>	Acute gout flare-6 mos, all other diagnoses-6 months initial, 1 year cont.
<b>Other Criteria</b>	For renewal of CAPS/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. Adult Onset Still's Disease-Initial-approve. 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). FMF, initial-approve if pt has tried colchicine, unless contraindicated and will be taking Ilaris in combination with colchicine, unless colchicine is contraindicated or not tolerated, AND prior to starting Ilaris, the patient meets BOTH of the

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>following (a and b): a) C-reactive protein level is greater than or equal to 10 mg/L OR elevated to at least two times the upper limit of normal AND b) pt has a history of at least one flare per month despite use of colchicine, OR was hospitalized for a severe flare. HIDS/MKD, initial-approve if prior to starting Ilaris, the patient meets BOTH of the following (a and b): a) C-reactive protein level is greater than or equal to 10 mg/L OR elevated to at least two times the upper limit of normal AND b) Pt has a history of at least three febrile acute flares within the previous 6-month period OR was hospitalized for a severe flare. TRAPS, initial-approve if prior to starting Ilaris, the patient meets BOTH of the following (a and b): a) C-reactive protein level is greater than or equal to 10 mg/L OR elevated to at least two times the upper limit of normal AND b) Pt has a history of at least six flares per year OR was hospitalized for a severe flare.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# ILUMYA

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## Products Affected

- ILUMYA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist (initial therapy)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	Initial Therapy - Approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya, Sotyktu. Continuation Therapy - Patient must have responded, as determined by the prescriber. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# IMAAVY

## Products Affected

- IMAAVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with another Neonatal Fc Receptor Blocker, a Complement Inhibitor, or a Rituximab Product
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older (initial and continuation)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist (initial and continuation)
<b>Coverage Duration</b>	Initial-6 months, continuation-1 year
<b>Other Criteria</b>	GENERALIZED MYASTHENIA GRAVIS, INITIAL-ALL of the following (A, B, C and D): A. Confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis or confirmed anti-muscle-specific tyrosine kinase antibody-positive generalized myasthenia gravis, AND B. Received or is currently receiving pyridostigmine or has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine, AND C. Evidence of unresolved symptoms of generalized myasthenia gravis, Note: Examples of unresolved symptoms include 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. Patients who are 18 years and older have 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. GENERALIZED MYASTHENIA GRAVIS, CONTINUATION-Approve if continuing to derive benefit.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# IMATINIB

## Products Affected

- GLEEVEC ORAL TABLET 100 MG, 400 MG
- imatinib oral tablet 100 mg, 400 mg*
- IMKELDI

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/Kaposi Sarcoma/Cutaneous Melanoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For ALL -approve for Ph-positive or ABL-class translocation ALL. CML-approve for Ph-positive or BCR::ABL1-mutation positive CML. 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 Romvimza or according to the prescriber, the patient cannot take Turalio or Romvimza. 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). Cutaneous melanoma-approve if the patient has an activating KIT mutation, metastatic or unresectable melanoma, and has tried at least one systemic regimen. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement or an FIP1L1-PDGFR 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 bioequivalent generic

<b>PA Criteria</b>	<b>Criteria Details</b>
	product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chordoma, desmoid tumors (aggressive fibromatosis), cKit positive metastatic or unresectable cutaneous melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic.
<b>Part B Prerequisite</b>	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]).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). 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
Part B Prerequisite	No

# IMDELLTRA

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## Products Affected

- IMDELLTRA

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. SMALL CELL LUNG CANCER-patient has relapsed or refractory extensive stage disease and has previously received platinum-based chemotherapy. Note: Examples of platinum medications include cisplatin and carboplatin.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	<p>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 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)</p>

PA Criteria	Criteria Details
	<p>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.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Esophageal and Esophagogastric Junction Cancers, Gastric Cancer
<b>Part B Prerequisite</b>	No



# IMPAVIDO

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## 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	Ameba related infections: approve if the patient is being treated for an infection due to one of the following: Acanthameoba, Balamuthia mandrillaris, or Naegleria fowleri. Note: Examples of ameba related infections are Acanthamoeba keratitis, granulomatous amebic encephalitis (GAE), and primary amebic meningoencephalitis (PAM).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ameba related infections
Part B Prerequisite	No

# INBRIJA

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## 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 and is experiencing off episodes.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# INFLECTRA

## Products Affected

- INFLECTRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medication, medications previously tried
<b>Age Restrictions</b>	CD/UC - Pts aged 6 years or more (initial therapy). PP - Pts aged 18 years or more (initial therapy)
<b>Prescriber Restrictions</b>	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)
<b>Coverage Duration</b>	FDAind init-3mo,cont1yr,GVHD init-1mo,cont-3mo,Pyo Gang-init4 mo,cont1yr,other-init3mo,cont-12 mo
<b>Other Criteria</b>	INITIAL THERAPY: RHEUMATOID ARTHRITIS: tried one conventional synthetic DMARD for at least 3 months (e.g., MTX, leflunomide, hydroxychloroquine, sulfasalazine. 3-month trial of a biologic also counts). CROHN'S DISEASE: approve. ULCERATIVE COLITIS: approve. BEHCET'S (A or B): A) tried one conventional therapy (e.g., systemic CS, immunosuppressants such as AZA, MTX, mycophenolate, CSA, tacrolimus, chlorambucil, cyclophosphamide, interferon alfa. TNF inhibitor also counts.) or B) ophthalmic manifestations. STILL'S DISEASE (A and B): A) tried one CS and B) tried one DMARD for at least 2 months or intolerant (e.g., MTX. Trial of a biologic also counts.) UVEITIS: tried periocular, intraocular or systemic CS or immunosuppressive (e.g., MTX, mycophenolate, CSA. Trial of a biologic also counts.) SARCOIDOSIS (A and B): A) tried one CS and B) tried one immunosuppressant (e.g., MTX, AZA, leflunomide, mycophenolate, hydroxychloroquine, chloroquine.) PYODERMA GANGRENOSUM (A or B): A) tried one systemic CS or B)

PA Criteria	Criteria Details
	<p>tried one immunosuppressant for at least 2 months or intolerant (e.g., mycophenolate, CSA). HIDRADENITIS SUPPURATIVA: Tried one other therapy (e.g., intralesional or oral CS, systemic antibiotics, isotretinoin). GRAFT VS HOST DISEASE: Tried one conventional systemic treatment (e.g., CS, antithymocyte globulin, CSA, tacrolimus, mycophenolate.) JUVENILE IDIOPATHIC ARTHRITIS: (A or B): A) tried one systemic medication (e.g., MTX, sulfasalazine, leflunomide, NSAID. Trial of a biologic also counts.) or B) has aggressive disease. PLAQUE PSORIASIS (A or B): A) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Trial of a biologic will also count) or B) contraindication to MTX. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy.</p>
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

# INGREZZA

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## Products Affected

- INGREZZA
- INGREZZA INITIATION PK(TARDIV)
- INGREZZA SPRINKLE

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
- AZMIRO
- 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, 12 years and older (testosterone cypionate)
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 or testosterone cypionate. Breast cancer in females-approve testosterone enanthate. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual with the biological traits of a woman,

<b>PA Criteria</b>	<b>Criteria Details</b>
	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).
<b>Part B Prerequisite</b>	No

# INLEXZO

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## Products Affected

- INLEXZO

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 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. NON-MUSCLE INVASIVE BLADDER CANCER-patient has carcinoma in situ (CIS) and Bacillus Calmette-Guerin (BCG)-unresponsive disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No



# INLYTA

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## Products Affected

- INLYTA ORAL TABLET 1 MG, 5 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	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 oncocytic) Thyroid Carcinoma, Soft tissue sarcoma
Part B Prerequisite	No

# INPEFA

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## Products Affected

- INPEFA

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

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## Products Affected

- INQOVI

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, 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. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid Neoplasms with Eosinophilia, accelerated or blast phase myeloproliferative neoplasm
Part B Prerequisite	No

# IQIRVO

## Products Affected

- IQIRVO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)
Coverage Duration	6 months initial, 1 year cont.
Other Criteria	<p>INITIAL THERAPY: PRIMARY BILIARY CHOLANGITIS-All of (i and ii): i. Diagnosis of primary biliary cholangitis as defined by TWO of the following (a, b, or c): a) Alkaline phosphatase is elevated above the upper limit of normal, OR b) Positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific auto-antibodies, including sp100 or gp210, if anti-mitochondrial antibodies are negative, OR c) Histologic evidence of primary biliary cholangitis from a liver biopsy, AND ii. Has been receiving ursodiol therapy for greater than or equal to 1 year and had an inadequate response or is unable to tolerate, Note: Examples: ursodiol generic tablets and capsules, Urso 250, Urso Forte, Actigall.</p> <p>CONTINUATION THERAPY: has demonstrated a response to therapy. Note: Examples of a response to therapy are improved biochemical markers of primary biliary cholangitis (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT]).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ISTURISA

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## 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	1 year
Other Criteria	Approve if (A, B, or C): A) the patient is not a candidate for surgery or surgery has not been curative, or B) patient is awaiting surgery for endogenous Cushing's syndrome, or C) patient is awaiting therapeutic response after radiotherapy for endogenous Cushing's syndrome.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ITOVEBI

## Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 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	<p>BREAST CANCER (all of A, B, C, D, E and F): A. Patient meets ONE of the following (i or ii): i. Patient is a postmenopausal female, OR ii. Patient meets BOTH of the following (a and b): a. Patient is a pre/perimenopausal female or a male, AND b. Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist OR had surgical bilateral oophorectomy or ovarian irradiation (female) or orchiectomy (male), Note: Examples of a GnRH agonist include leuprolide acetate, leuprolide acetate intramuscular injection, triptorelin pamoate intramuscular injection, goserelin acetate subcutaneous injection. AND B. Patient has locally advanced or metastatic hormone receptor (HR)-positive disease, AND C. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D. Patient has PIK3CA-mutated breast cancer as detected by an approved test, AND E. Patient meets (i or ii): i) has disease progression while on adjuvant endocrine therapy or ii) had disease recurrence within 12 months after completing adjuvant endocrine therapy, Note: Examples of endocrine therapy include tamoxifen, anastrozole, letrozole, exemestane, toremifene. AND F. The medication will be used in combination with palbociclib capsules/tablets and fulvestrant injection.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No



# IVERMECTIN (ORAL)

## Products Affected

- ivermectin oral tablet 3 mg, 6 mg
- STROMEKTOL

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

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## Products Affected

- ALYGLO
- ASCENIV
- BIVIGAM
- 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

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## 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

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## Products Affected

- IZERVAY (PF)

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-1 to 21 years of age, GVHD-12 and older, MF/PV/accelerated or blast phase MPN/CMML-2/essential thrombo/myeloid/lymphoid neoplasm/T-cell Lymphoma-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 or Besremi (ropeginterferon alfa-2b-njft subcutaneous injection). 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. 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. T-Cell Lymphoma - approve if pt has (A or B): A) peripheral T-cell lymphoma or B) meets (i and ii): i) pt has T-cell prolymphocytic leukemia, T-cell large granular lymphocytic leukemia, hepatosplenic T-cell lymphoma, or breast implant-associated anaplastic large cell lymphoma and ii) pt has tried at least one systemic regimen. Accelerated or blast phase myeloproliferative neoplasm-approve if pt has at least one disease-related symptom (examples: fatigue, fever, night sweats,

<b>PA Criteria</b>	<b>Criteria Details</b>
	weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms, T-Cell lymphoma, accelerated or blast phase myeloproliferative neoplasm
<b>Part B Prerequisite</b>	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	<p>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, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, Velcade (bortezomib intravenous or subcutaneous injection), lenalidomide, gemcitabine, and Venclexta (venetoclax tablets). Note: Examples of BTK inhibitors indicated for mantle cell lymphoma include Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib capsules), and Imbruvica (ibrutinib capsules, tablets, and oral suspension). CLL/SLL-patient meets (A or B): A) patient has resistance or intolerance to Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules) or B) patient has relapsed or refractory disease and has tried a Bruton tyrosine kinase (BTK) inhibitor and Venclexta (venetoclax tablet)-based regimen. Examples of BTK inhibitor include: Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules). Richter's Transformation to DLBCL- pt has tried at least one chemotherapy regimen or is not a candidate for a chemotherapy</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	regimen. Marginal Zone Lymphoma - approve if pt has tried at least one Bruton tyrosine kinase inhibitor.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Richter's Transformation to Diffuse Large B-Cell Lymphoma, Marginal Zone Lymphoma
<b>Part B Prerequisite</b>	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 Adenocarcinoma-approve if the patient has dMMR or MSI-H disease or DNA polymerase epsilon/delta (POLE/POLD1) mutation 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 or DNA polymerase epsilon/delta (POLE/POLD1) mutation AND has advanced or metastatic disease AND is being used for neoadjuvant therapy or primary or subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Small Bowel Adenocarcinoma, Colon, Rectal or Appendiceal Cancer

PA Criteria	Criteria Details
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, geneticist or an infectious diseases physician who treats patients with primary immune deficiencies (initial)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	<p>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 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</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	size, immunoglobulin replacement therapy use, infection rate, or immunoglobulin M (IgM) levels.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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	N/A
Coverage Duration	12 months
Other Criteria	<p>HYPERLIPIDEMIA WITH HoFH (all of A, B, and C): A) meets (a or b): a) phenotypic confirmation of HoFH, or b) meets (i and ii): i) untreated LDL-C greater than 400 mg/dL or treated LDL-C greater than or equal to 300 mg/dL, and ii) clinical manifestations of HoFH before 10 years of age or at least one parent with untreated LDL-C or total cholesterol consistent with FH, AND B) meets (a or b): a) tried a PCSK9 inhibitor for at least 8 weeks and LDL-C remains 70 mg/dL or higher, or b) has two LDL-receptor negative alleles, AND C) meets (a or b): a) tried one high-intensity statin and ezetimibe and LDL-C remains 70 mg/dL or higher or b) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# JYNARQUE

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## Products Affected

- JYNARQUE
- tolvaptan (polycys kidney dis)*

PA Criteria	Criteria Details
Exclusion Criteria	Patient is currently receiving another tolvaptan product.
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

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## 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 meet A, B, and C: A) pt must have one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# KANUMA

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## 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 biallelic pathogenic or likely pathogenic lysosomal acid lipase gene variants.
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	<p>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 or has experienced significant intolerance 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 m<sup>2</sup> 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 angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b) According to the prescriber, patient has a contraindication or has experienced significant intolerance to ACE inhibitor and ARB therapy. Heart failure-initial-Pt meets all (i, ii, and iii): i) has left ventricular ejection fraction of at least 40 percent AND ii) tried one of the following SGLT-2 inhibitors: Farxiga (dapagliflozin tabs, authorized generic) Inpefa (sotagliflozin tabs), or Jardiance (empagliflozin tabs) OR has contraindication or has experienced</p>

PA Criteria	Criteria Details
	significant intolerance to SGLT-2 inhibitors AND iii) at baseline (prior to initiation of Kerendia), meets all (a and b): a) estimated glomerular filtration rate of at least 25 mL/min/1.73m <sup>2</sup> AND b) serum potassium level of less than or equal to 5.0 mEq/L. Heart failure-continuation-Pt meets all (i and ii): i) has left ventricular ejection fraction of at least 40 percent AND ii) tried one of the following SGLT-2 inhibitors: Farxiga (dapagliflozin tabs, authorized generic) Inpefa or (sotagliflozin tabs), or Jardiance (empagliflozin tabs) or has contraindication or has experienced significant intolerance to SGTL-2 inhibitors.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# KESIMPTA

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## Products Affected

- KESIMPTA PEN

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

# KEVEYIS

## Products Affected

- *dichlorphenamide*
- KEVEYIS
- *ormalvi*

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	<p>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 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</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	responded to dichlorphenamide (e.g., decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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 end of plan year
Other Criteria	<p>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, a preferred adalimumab product, 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. 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. PJIA initial - approve if the patient has tried TWO of the following drugs in the past: Enbrel, Orencia, Rinvoq, Xeljanz, or a preferred adalimumab product. (Note: if the patient does not meet this requirement, a previous trial with infliximab, a non-preferred adalimumab, or a tocilizumab product also counts toward meeting the try two requirement.) Cont tx - pt must have had a response to therapy. Polymyalgia rheumatica, initial-approve if the patient has tried one systemic corticosteroid. Cont tx-pt must have had a response to therapy. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma.</p>
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	Melanoma - 12 and older, Glioma - less than 18 years, all others- 18 and older (except Merkel cell, MSI-H/dMMR tumors, large B-cell lymph, TMB-H)
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, 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, ovarian/fallopian tube/peritoneal cancer, small bowel adenocarcinoma, thyroid carcinoma, vaginal cancer, chronic lymphocytic leukemia/small lymphocytic leukemia, penile cancer
Part B Prerequisite	No

# KEYTRUDA QLEX

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## Products Affected

- KEYTRUDA QLEX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Merkel cell carcinoma/TMB-H cancer - 12 and older. All others - 18 and older (except MSI-H/dMMR solid tumors)
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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Thymic carcinoma
Part B Prerequisite	No

# KINERET

## Products Affected

- KINERET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another biologic DMARD or targeted synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	RA initial. Approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, 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.] DIRA initial-approve if genetic testing has confirmed a mutation in the IL1RN gene. Adult Onset Still's Disease, approve. SJIA-initial-approve. cont tx - approve if the patient had responded to therapy as determined by the prescriber. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Adult onset Still's disease (SD). Systemic Juvenile Idiopathic Arthritis (SJIA)

PA Criteria	Criteria Details
Part B Prerequisite	No

# KISQALI

## Products Affected

- KISQALI FEMARA CO-PACK ORAL TABLET 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	<p>Breast cancer - approve for hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative early (stage II or III), recurrent, or metastatic breast cancer [for early breast cancer must be adjuvant treatment and high risk of recurrence] when the pt meets ONE of the following</p> <ol style="list-style-type: none"> <li>1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole</li> <li>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</li> <li>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.</li> <li>4. Patient is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole.</li> </ol> <p>Endometrial cancer - approve if pt meets all of (A,</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	B and C): A) pt has recurrent or metastatic disease, and B) has estrogen receptor (ER)-positive tumors, and C) if request is for Kisqali (not Co-Pack), Kisqali will be used in combination with letrozole.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Endometrial cancer
<b>Part B Prerequisite</b>	No



# KISUNLA

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## Products Affected

- KISUNLA

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	ALZHEIMER'S DISEASE- Clinical diagnosis of mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease, AND amyloid beta pathology consistent with Alzheimer's disease, AND receiving the medication as part of either (A or B): A) prospective comparative study and the study is CMS-approved or B) 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

# 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	1 year
Other Criteria	Endogenous Cushing's Syndrome-Approve if mifepristone is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance AND pt meets (i, ii or iii): i) patient is not a candidate for surgery or surgery has not been curative, or (ii) patient is awaiting surgery for endogenous Cushing's Syndrome or (iii) patient is awaiting therapeutic response after radiotherapy for endogenous Cushing's Syndrome.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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	<p>Neurofibromatosis Type 1-approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas and if the patient is 1 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 lesions, OR iv. Patient has central nervous system disease, AND B) The medication is used as a single agent.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Circumscribed Glioma, Langerhans Cell Histiocytosis
<b>Part B Prerequisite</b>	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	<p>Non-Small Cell Lung Cancer (NSCLC)-approve if (A and B): A) the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND B) patient meets either (i or ii): i) has been previously treated with at least one systemic regimen [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.] or ii) patient has brain metastases. 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 previously received a chemotherapy regimen for colon or rectal cancer. Ampullary adenocarcinoma-approve if (A, B and C): A) metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy. Biliary tract cancer- approve if (A, B and C): A) unresectable or metastatic disease, B) KRAS G12C mutation-positive disease, and C) previously treated with at least one systemic regimen. Pancreatic adenocarcinoma- approve if (A and B): A) KRAS G12C mutation-positive</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	disease, and B) either (i or ii): (i) locally advanced or metastatic disease and previously treated with at least one systemic regimen, or (ii) recurrent disease after resection. Small bowel adenocarcinoma- approve if (A, B and C): A) advanced or metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Ampullary adenocarcinoma, biliary tract cancer, pancreatic adenocarcinoma, small bowel adenocarcinoma
<b>Part B Prerequisite</b>	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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
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 SUBCUTANEOUS SYRINGE 120 MG/0.5 ML
- 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). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)-approve. Carcinoid Syndrome/Pheochromocytoma/paraganglioma-approve.
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+ disease and the patient is a postmenopausal woman or the patient is premenopausal or perimenopausal woman and is receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian irradiation OR the patient is a man and is receiving a GnRH analog. Colon or rectal cancer-approve if the patient has unresectable advanced or metastatic disease that is human epidermal receptor 2 (HER2) amplified and with wild-type RAS and BRAF disease and the patient has tried at least one chemotherapy regimen or is not a candidate for intensive therapy and the medication is used in combination with trastuzumab (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan) and the patient has not been previously treated with a HER2-inhibitor. Bone Cancer-approve if the patient has recurrent chordoma and if the patient has epidermal growth-factor receptor (EGFR)-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone cancer-chordoma, colon or rectal cancer, breast cancer in pre/perimenopausal women and men

PA Criteria	Criteria Details
Part B Prerequisite	Yes

# LAZCLUZE

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## Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 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	NON-SMALL CELL LUNG CANCER-ALL of the following (A, B, C, and D): A. Locally advanced or metastatic disease, AND B. Epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test, AND C. Used in combination with Rybrevant, AND D. Used as first-line treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# LEDIPASVIR/SOFOSBUVIR

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## Products Affected

- LEDIPASVIR-SOFOSBUVIR

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	Diagnosis
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.
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
<b>Exclusion Criteria</b>	Current Use of Lemtrada with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS). Patients with HIV infection.
<b>Required Medical Information</b>	Diagnosis, Previous medication use
<b>Age Restrictions</b>	MS - 17 years of age and older (initial and continuation)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS (initial and continuation)
<b>Coverage Duration</b>	MS, has not completed 1 course of Lemtrada-5 doses. MS, has completed prior course Lemtrada-3 doses
<b>Other Criteria</b>	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, a natalizumab IV product, Briumvi, Mavenclad, Lemtrada or Ocrevus/Ocrevus Zunovo 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 aggressive 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 elapsed from the last dose of any prior Lemtrada treatment course for relapsing MS.
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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	<p>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. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve. 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. Histiocytic</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	neoplasms-approve if the patient has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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, histiocytic neoplasms.
<b>Part B Prerequisite</b>	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	<p>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 mismatch repair proficient (pMMR) or 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 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-</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy. Anaplastic thyroid carcinoma-approve if the medication is used in combination with Keytruda (pembrolizumab intravenous infusion).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Melanoma, Anaplastic thyroid carcinoma
<b>Part B Prerequisite</b>	No

# LEQEMBI

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## Products Affected

- LEQEMBI
- LEQEMBI IQLIK

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

# LEQSELVI

## Products Affected

- LEQSELVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with an oral or topical Janus Kinase Inhibitor (JAKi), a biologic immunomodulator or other potent immunosuppressants (e.g., cyclosporine, azathioprine)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial/continuation)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist (initial therapy)
<b>Coverage Duration</b>	Initial-6 months, Continuation-1 year
<b>Other Criteria</b>	INITIAL THERAPY, ALOPECIA AREATA-All of (A, B and C): A. Patient is not a cytochrome P450 2C9 poor metabolizer, AND B. Current episode of alopecia areata lasting for greater than or equal to 6 months, AND C. Greater than or equal to 50% scalp hair loss. CONTINUATION, ALOPECIA AREATA-patient has been established on Leqselvi for at least 6 months, has experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Leqselvi) in extent and density of scalp hair loss and the patient continues to require systemic therapy for the treatment of alopecia areata.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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	N/A
Coverage Duration	1 year
Other Criteria	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL, b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, AND B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below).</p> <p>ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD or HeFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. FOR ALL INDICATIONS: must try Repatha prior to approval of Leqvio. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Established Cardiovascular Disease
<b>Part B Prerequisite</b>	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	<p>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 and meets one of the following (i, ii, iii, or iv): (i): medication is used for first-line or continuation maintenance therapy AND tumor is negative for actionable mutations (however, may be KRAS G12C mutation positive), or (ii): medication will be used first line AND the tumor is positive for one of EGFR exon 20 mutation or ERBB2 (HER2) mutation, or (iii): medication will be used as first-line or subsequent therapy AND the tumor is positive for one of BRAF V600E mutation or NTRK1/2/3 gene fusion or MET exon 14 skipping mutation or RET rearrangement, or (iv): medication will be used as subsequent therapy AND the tumor is positive for one of EGFR S768I, L861Q, and/or G719X mutation or EGFR exon 19 deletion or exon 21 L858R or ALK rearrangement or ROS1 rearrangement AND pt has received targeted drug therapy for the specific mutation. Cervical cancer-approve if pt has local or regional recurrence or distant metastatic disease</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	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. Vaginal cancer- approve if pt meets (A and B): A) meets (i or ii): i) local or regional recurrence, or ii) distant metastatic disease, and B) used as subsequent therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Cervical cancer, vulvar cancer, vaginal cancer
<b>Part B Prerequisite</b>	No

# LIDOCAINE PATCH

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## Products Affected

- *dermacinrx lidocan*
- *lidocaine topical adhesive patch,medicated 5 %*
- *lidocan iii*
- *lidocan iv*
- *lidocan v*
- *tridacaine ii*
- *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

# LITFULO

## Products Affected

- LITFULO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with an oral or topical Janus Kinase Inhibitor (JAKi), a biologic immunomodulator or other potent immunosuppressants (e.g., cyclosporine, azathioprine)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist (initial therapy)
<b>Coverage Duration</b>	Initial-6 months, Continuation-1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LIVDELZI

## Products Affected

- LIVDELZI

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Iqirvo
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)
Coverage Duration	6 months initial, 1 year cont.
Other Criteria	<p>INITIAL THERAPY: PRIMARY BILIARY CHOLANGITIS/CIRRHOSIS-All of (A and B): A): Diagnosis confirmed by TWO of the following i, ii, or iii: i) Alkaline phosphatase is elevated above the upper limit of normal, ii) positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific auto-antibodies, including sp100 or gp210, if anti-mitochondrial antibodies are negative or iii) histologic evidence of primary biliary cholangitis from a liver biopsy, B): Receiving ursodiol therapy for greater than or equal to 1 year and had inadequate response or was unable to tolerate ursodiol therapy. Note: examples of ursodiol therapy include ursodiol generic tablets and capsules, Urso 250, Urso Forte, and Actigall. CONTINUATION THERAPY: PRIMARY BILIARY CHOLANGITIS/CIRRHOSIS- patient has demonstrated a response to therapy. Note: Examples of a response to therapy are improved biochemical markers of primary biliary cholangitis (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT]).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# LIVMARLI

## Products Affected

- LIVMARLI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Alagille Syndrome- 3 months and older (initial therapy), PFIC-12 months and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or a physician who specializes in Alagille syndrome or PFIC, respectively (initial and continuation)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	<p>Alagille Syndrome, initial-approve if the patient meets (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 has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory AND iv. pt does not have cirrhosis, portal hypertension or history of a hepatic decompensation event.</p> <p>Alagille Syndrome, continuation-approve if the patient has had a response to therapy. PFIC, initial-approve if the patient meets (i, ii, iii and iv): i. Patient has moderate-to-severe pruritus, according to prescriber AND ii. Diagnosis of PFIC was confirmed by genetic testing demonstrating a gene mutation affiliated with PFIC (including ATP8B1 gene, ABCB11 gene, ABCB4 gene, TJP2 gene, NR1H4 gene, and MYO5B gene) AND iii. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory AND iv. pt does not have cirrhosis, portal hypertension or history of a hepatic decompensation event. PFIC, continuation- approve if the patient has had a response to therapy.</p>
Indications	All FDA-approved Indications.



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

# LIVTENCITY

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## 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 ORAL TABLET,ORAL ONLY,EXT.REL.24 HR 100 MG, 20 MG, 30 MG, 40 MG, 60 MG, 80 MG
- *methadone intenosol*
- *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*
- *morphine oral tablet extended release*
- MS CONTIN ORAL TABLET EXTENDED RELEASE 15 MG, 30 MG, 60 MG
- NUCYNTA ER
- OXYCODONE ORAL TABLET,ORAL ONLY,EXT.REL.12 HR 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.
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

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

# LONSURF

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## 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 fluopyrimidine, 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	<p>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 or in combination with cisplatin and gemcitabine. Anal carcinoma- approve if patient meets (A and B): A) meets (i or ii): i) locally recurrent, progressive disease and medication is administered before proceeding to abdominoperineal resection, or ii) metastatic disease, medication is used as subsequent therapy and patient has not received prior immunotherapy [ex: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Libtayo (cemiplimab intravenous infusion), and Jemperli (dostarlimab intravenous infusion)], and B) medication is used as a single agent. Small bowel adenocarcinoma- approve if patient meets (A, B, C and D): A) locally unresectable or medically inoperable disease, B) ultra-hypermutated phenotype (defined as tumor mutation burden greater than 50 mutations/megabase), C) patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H)</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	disease or polymerase epsilon/delta (POLE/POLD1) mutation positive disease, and D) medication is used as a single agent.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anal carcinoma, small bowel adenocarcinoma
<b>Part B Prerequisite</b>	No



# LORBRENA

## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, ALK status, ROS1 status, previous therapies
<b>Age Restrictions</b>	Pediatric Diffuse High-Grade Glioma- less than 18 years old, All others- 18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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. NSCLC-ROS1 Rearrangement-Positive, advanced or metastatic NSCLC-approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib. Large B-Cell Lymphoma- approve if ALK-positive disease and disease is relapsed or refractory. Pediatric Diffuse High-Grade Glioma- approve if ALK-positive disease and (i or ii): i) used as adjuvant therapy, or ii) used for recurrent or progressive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive, Erdheim Chester Disease, Inflammatory Myofibroblastic Tumor (IMT), Large B-Cell Lymphoma, Pediatric Diffuse High-Grade Glioma
<b>Part B Prerequisite</b>	No

# LUCEMYRA

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## Products Affected

- *lofexidine*
- 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

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## 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	Approve if the patient has tried Cimerli or Byooviz and cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Retinopathy of prematurity
Part B Prerequisite	No

# LUMAKRAS

## Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 240 MG, 320 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	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. Ampullary adenocarcinoma - approve if pt has KRAS G12C-mutated disease as determined by an approved test AND this is used as subsequent therapy. Colon or rectal cancer - approve if pt meets all (A, B, C and D): A) unresectable, advanced, or metastatic disease, and B) KRAS G12C mutation-positive disease, and C) medication is prescribed as part of a combination regimen for colon or rectal cancer [Ex: Lumakras plus cetuximab or panitumumab] or patient is unable to tolerate combination therapy, and D) previously received a chemotherapy regimen for colon or rectal cancer. 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, Ampullary Adenocarcinoma

PA Criteria	Criteria Details
Part B Prerequisite	No

# LUMIZYME

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## 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 biallelic pathogenic or likely pathogenic acid alpha-glucosidase (GAA) gene variants.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# LUMRYZ

## Products Affected

- LUMRYZ
- LUMRYZ STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of sodium oxybate, Xywav, Wakix, Sunosi
Required Medical Information	Diagnosis
Age Restrictions	7 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 (not required if the patient is less than 18 years of age) 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 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. Follicular Lymphoma-approve if the patient has received at least two lines of systemic therapy. Note: Examples of systemic therapy for follicular lymphoma include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (obinutuzumab intravenous infusion) and CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva. B-Cell Lymphoma (examples: diffuse large B-cell lymphoma, high-grade B-cell lymphoma, HIV-related B-cell lymphomas, post-transplant lymphoproliferative disorders)- approve if patient has received at least one line of systemic therapy and will be used in combination with Polivy. Note: Examples of systemic therapy for B-Cell lymphoma include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and Pola-R-CHP (Polivy [polatuzumab vedotin-piiq intravenous infusion], rituximab, cyclophosphamide, doxorubicin, prednisone).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	B-Cell Lymphoma
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	<p>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/m<sup>2</sup> C) the diagnosis of lupus nephritis has been confirmed on biopsy. Note: For example, World Health Organization class III, IV, or V lupus nephritis.</p> <p>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.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# LUPRON DEPOT

## Products Affected

- LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)
- LUPRON DEPOT (6 MONTH)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Premenstrual disorders - 18 years and older
<b>Prescriber Restrictions</b>	Prostate cancer-prescribed by/consultation with oncologist or urologist. Other cancer diagnosis- prescribed by/consultation with an oncologist. Gender dysphoria/reassignment- prescribed by/consultation with endocrinologist or physician who specializes in treatment of transgender patients
<b>Coverage Duration</b>	uterine leiomyomata - 3 months, abnormal uterine bleeding - 6 months, all others - 12 months
<b>Other Criteria</b>	Endometriosis-approve if the pt has tried one of the following, unless contraindicated: a contraceptive, an oral progesterone or depo-medroxyprogesterone injection. An exception can be made if the pt has previously tried a gonadotropin-releasing hormone [GnRH] agonist (e.g. Lupron Depot) or antagonist (e.g. Orilissa). Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease. Premenstrual disorders including PMS and PMDD- approve if pt has severe refractory premenstrual symptoms AND pt has tried an SSRI or combined oral contraceptive. Prostate cancer - for patients new to therapy requesting Lupron 7.5 mg, 22.5 mg, 30 mg or 45 mg, patients are required to try Orgovyx or Eligard prior to approval.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	abnormal uterine bleeding, breast cancer, gender dysphoria/gender reassignment, head and neck cancer-salivary gland tumors, ovarian cancer including fallopian tube and primary peritoneal cancers, premenstrual disorders including premenstrual syndrome and premenstrual dysphoric

PA Criteria	Criteria Details
	disorder, prophylaxis or treatment of uterine bleeding or menstrual suppression in pts with hematologic malignancy or undergoing cancer treatment or prior to bone marrow or stem cell transplant, uterine cancer
<b>Part B Prerequisite</b>	No

# LYNOZYFIC

## Products Affected

- LYNOZYFIC

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	<p>Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. MULTIPLE MYELOMA-all of the following (A and B): A) Tried at least four systemic regimens, AND B) Among the previous regimens tried, the patient has received at least one drug from each of the following classes (i, ii, and iii): i. Proteasome inhibitor, Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules) AND ii. Immunomodulatory drug, Note: Examples include lenalidomide, Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules) AND iii. Anti-CD38 monoclonal antibody, Note: Examples include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), or Sarclisa (isatuximab-irfc intravenous infusion).</p>
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 has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND The patient is in complete or partial response to at least one platinum-based chemotherapy regimen (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has recurrent or metastatic disease and has (i or ii): i) germline BRCA mutation-positive breast cancer or ii) germline PALB2 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

<b>PA Criteria</b>	<b>Criteria Details</b>
	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 at least one systemic regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Uterine Leiomyosarcoma
<b>Part B Prerequisite</b>	No

# LYTGOBI

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## Products Affected

- LYTGOBI ORAL TABLET 12 MG/DAY (4 MG X 3), 16 MG/DAY (4 MG X 4), 20 MG/DAY (4 MG X 5)

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

# 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
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agents used for multiple sclerosis
<b>Required Medical Information</b>	Diagnosis, other medications that will be used in combination
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial treatment-approve if the patient has tried one S1P drug (Gilenya or Zeposia) AND one fumarate product (generic dimethyl fumarate or Vumerity) prior to approval of Mavenclad. Regarding fumarate products-Prior use of brand Tecfidera or Bafiertam also counts as a fumarate product. A trial of a glatiramer product (Copaxone, Glatopa, generic) can bypass the fumarate requirement. Regarding S1P products-Prior use of a Non-preferred S1P (e.g., Ponvory, Mayzent) also counts as a trial of a S1P. Patients 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 product. If the patient has experienced inadequate efficacy or significant intolerance to one of Kesimpta (ofatumumab subcutaneous injection), a natalizumab intravenous (IV) product (Tysabri, biosimilar), Briumvi (ublituximab-xiij IV infusion), Lemtrada (alemtuzumab IV infusion), Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq subcutaneous injection) or Ocrevus (ocrelizumab IV infusion) a trial of a S1P and fumarate product is not required. Cont tx-approve if the patient has received Mavenclad in the past.
<b>Indications</b>	All FDA-approved Indications.



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

# MAVYRET

## Products Affected

- MAVYRET ORAL PELLETS IN PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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	Chronic HCV- Criteria will be applied consistent with AASLD/IDSA guidance, Acute HCV-8 weeks
Other Criteria	For Chronic Hepatitis C Virus, criteria will be applied consistent with current AASLD/IDSA guidance. For Acute Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6: Approve if the patient meets (A, B and C): A) Does not have cirrhosis OR has compensated cirrhosis AND B) has quantifiable HCV RNA AND C) ONE of the following (i, ii, or iii): i. conversion of negative to positive results in anti-HCV antibody, HCV RNA, and/or HCV core antigen OR ii. signs and symptoms of acute hepatitis C virus OR iii. has engaged in a risk behavior for HCV infection within the prior 6 months.
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
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agents used for multiple sclerosis
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# MEGESTROL

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## 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 Tafenlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafenlar, 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 Tafenlar. 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 Tafenlar. 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) glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR

PA Criteria	Criteria Details
	<p>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 Tafenlar (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 Tafenlar (dabrafenib capsules), AND C) Patient has no satisfactory alternative treatment options.  Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Tafenlar. Small bowel adenocarcinoma, approve if pt has BRAF V600E mutation-positive advanced or metastatic disease and this will be used with Tafenlar AND (i or ii): i) this will be used as initial therapy and pt has received previous FOLFOX/CAPEOX therapy in the adjuvant setting within the past 12 months or has a contraindication, or (ii) this will be used as second-line and subsequent therapy.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Histiocytic Neoplasm, Hairy Cell Leukemia
<b>Part B Prerequisite</b>	No

# MEKTOVI

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## 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

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## Products Affected

- *memantine oral capsule, sprinkle, er 24hr*
- *memantine oral solution*
- *memantine oral tablet*
- MEMANTINE ORAL TABLETS, DOSE PACK
- *memantine-donepezil*
- NAMZARIC ORAL CAPSULE, SPRINKLE, ER 24HR

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

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## 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 biallelic pathogenic or likely pathogenic glucuronidase gene variants.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# METHYLERGONOVINE

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## 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	NPC - greater than or equal to 2 years of age
Prescriber Restrictions	Gaucher Disease- 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. NPC- prescribed by or in consultation with a geneticist, endocrinologist, metabolic disorder subspecialist, or a physician who specializes in the treatment of NPC 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 ??-glucocerebrosidase activity in leukocytes or fibroblasts, OR ii. Molecular genetic testing documenting glucocerebrosidase gene mutation. NPC- approve if diagnosis is established by a molecular genetic test showing biallelic pathogenic variants in either the NPC1 or NPC2 gene.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Niemann-Pick Disease Type C (NPC)
Part B Prerequisite	No

# MIPLYFFA

## Products Affected

- MIPLYFFA

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Aqneursa
Required Medical Information	Diagnosis
Age Restrictions	2 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, metabolic disorder subspecialist, neurologist, or a physician who specializes in the treatment of Niemann-Pick disease type C or related disorders (initial and continuation)
Coverage Duration	1 year
Other Criteria	INITIAL, NIEMANN-PICK DISEASE TYPE C - All of (A, B, C, D and E): A. One or more neurological symptom(s) of Niemann-Pick disease type C, Note: Examples of neurologic symptoms of Niemann-Pick disease type C include loss of motor function, swallowing, and speech and cognitive impairment. AND B. Patient can walk independently or with assistance, AND C. Diagnosis is established by a genetic test showing biallelic pathogenic variants in either the NPC1 gene or NPC2 gene, AND D. Patient does NOT have adult-onset Niemann-Pick disease type C, Note: Adult-onset NPC is defined as the age of the first neurological symptom occurring greater than 15 years of age. AND E. Meets ONE of the following (i or ii): i. Medication will be taken in combination with miglustat, OR ii. Patient is unable to take miglustat. CONTINUATION, NIEMANN-PICK DISEASE TYPE C- All of (A, B and C): A.Patient does NOT have adult-onset Niemann-Pick disease type C, Note: Adult-onset NPC is defined as the age of the first neurological symptom occurring greater than 15 years of age. AND B. Meets ONE of the following (i or ii): i. Medication will be taken in combination with miglustat, OR ii. Patient is unable to take miglustat. AND C. Patient has derived benefit from treatment.
Indications	All FDA-approved Indications.

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

# MIRCERA

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## Products Affected

- MIRCERA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Hemoglobin level (initial level and after therapy if applicable), medication history for indication
Age Restrictions	CKD, no dialysis-3 months and older (intial)
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Anemia in CKD for patients not on dialysis-initial therapy, Hb is less than 10.0 g/dL. For patients currently receiving Mircera, epoetin alfa injection or Aranesp (darbepoetin alfa injection), Hb is less than or equal to 12.0 g/dL AND, if pt is less than 18 years old, according to the prescriber the Hb level has been stabilized by treatment with an ESA. For all covered uses, the patient is required to try Procrit or Retacrit before Mircera.
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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Excessive daytime sleepiness associated with narcolepsy-prescribed by or in consultation with a sleep specialist physician or neurologist
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Excessive daytime sleepiness (EDS) associated with myotonic dystrophy (modafinil only). Adjunctive/augmentation for treatment of depression in adults (modafinil only).
<b>Part B Prerequisite</b>	No

# MODEYSO

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## Products Affected

- MODEYSO

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	HIGH-GRADE GLIOMA (Note: Examples of high-grade glioma include World Health Organization (WHO) Grade 3 or 4 gliomas, such as diffuse midline glioma or glioblastoma)-all the following (A, B and C): A) Histone 3 (H3) K27M mutation, AND B) Recurrent or progressive disease, AND C) Received at one least prior therapy. Note: Examples of prior therapy include radiation, temozolomide, procarbazine, lomustine, or vincristine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No



# MONJUVI

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## 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 has been treated with at least one prior chemotherapy regimen. B-cell lymphoma-Approve if the patient has been treated with at least one prior chemotherapy regimen. Follicular lymphoma - approve if pt meets (A and B): A) pt has been treated with at least one prior systemic regimen and B) medication will be used in combination with lenalidomide and rituximab.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	B-Cell Lymphoma
Part B Prerequisite	No

# MULPLETA

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## 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 $50 \times 10^9/L$ AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy. In addition, patients must have a trial of Doptelet prior to Mulpleta, unless the patient has already started a course of therapy with Mulpleta for the upcoming procedure.
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	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or a geneticist physician specialist. For congenital generalized lipodystrophy where genetic testing did not demonstrate the clinical diagnosis, must have a specialist with experience in treating patients with lipodystrophy.
Coverage Duration	Authorization will be for 1 year
Other Criteria	If the patient has congenital generalized lipodystrophy, patient must have had a genetic test demonstrating one gene mutation (i.e., AGPAT2, BSCL2, CAV1, or PTRF) confirming the diagnosis of congenital generalized lipodystrophy, OR the clinical diagnosis of congenital generalized lipodystrophy has been made by a specialist with experience in treating patients with lipodystrophy. For both congenital or acquired generalized lipodystrophy, the patient must have experienced one or more manifestations of leptin deficiency.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# MYCAPSSA

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## 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, levonorgestrel-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 suspension]) or Orilissa (elagolix tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# MYOBLOC

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## Products Affected

- MYOBLOC

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic uses
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Upper Limb Spasticity - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Upper Limb Spasticity
Part B Prerequisite	No

# NAGLAZYME

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## 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 biallelic pathogenic or likely pathogenic arylsulfatase B gene variants.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# NAYZILAM

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## 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



# NEMLUVIO

## Products Affected

- NEMLUVIO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy
Required Medical Information	Diagnosis
Age Restrictions	AD: 12 years and older (initial therapy), PN: 18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
Coverage Duration	Initial-4 months, Continuation-1 year
Other Criteria	<p>INITIAL CRITERIA: ATOPIC DERMATITIS-All of (A, B and C): A) AD involvement estimated greater than or equal to 10 percent BSA, B) tried at least one medium to super-high potency topical corticosteroid (CS), unless topical CS therapy is not advisable, and C) will be used with a topical CS and/or topical calcineurin inhibitor or AD has improved sufficiently with Nemluvio and topical therapy has been discontinued.</p> <p>PRURIGO NODULARIS-All of (A, B and C): A) Pruritis for greater than or equal to 6 weeks, AND B) Meets i or ii: i) prurigo nodularis is NOT medication induced or secondary to a non-dermatologic condition such as neuropathy or a psychiatric disease, OR ii) secondary cause of prurigo nodularis has been identified and adequately managed AND C) Tried at least one high- or super-high potency prescription topical corticosteroid and experienced inadequate efficacy.</p> <p>CONTINUATION CRITERIA: ATOPIC DERMATITIS-patient has received at least 4 months of therapy with Nemluvio and has responded to therapy. PRURIGO NODULARIS-patient has received at least 4 months of therapy with Nemluvio, and experienced beneficial clinical response defined by ONE of the following (A, B, or C): A) reduced nodular lesion count, OR B) Decreased pruritus, OR C) Reduced nodular lesion size. Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Nemluvio should be considered under initial therapy. In addition, for all covered dx,</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	patients new to therapy are required to try Dupixent prior to approval of Nemluvio.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NERLYNX

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## Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Stage of cancer, HER2 status, previous or current medications tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Adjuvant tx-Approve for 1 year (total), advanced or metastatic disease-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	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy-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 meets one of the following: 1) 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), 2) 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 3) 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 Fulphila and Nyvepria and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse

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

# NEUPOGEN

## Products Affected

- NEUPOGEN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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, Radiation-1 mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)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), 2)patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver or renal dysfunction, poor performance status, HIV infection), 3)patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy, has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia

PA Criteria	Criteria Details
	<p>[absolute neutrophil count less than 100 cells/mm<sup>3</sup>], neutropenia expected to be greater than 10 days in duration, invasive fungal infection). For all diagnoses (except PBPC and radiation syndrome): Patients are required to try Releuko and Nivestym and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Neupogen unless patient has initiated therapy with Neupogen and requires additional medication to complete the current cycle of chemotherapy. For PBPC, patients are required to try Nivestym and cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Neupogen unless patient has initiated therapy with Neupogen and requires additional medication to complete the current cycle of chemotherapy.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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).
<b>Part B Prerequisite</b>	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	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL, b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, AND B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and ezetimibe and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and ezetimibe and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD or HeFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of</p>



<b>PA Criteria</b>	<b>Criteria Details</b>
	atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL, b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, AND B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below).</p> <p>ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD or HeFH) [A or B]: A) tried one high-intensity statin for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of</p>

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

# NEXVIAZYME

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## 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 biallelic pathogenic or likely pathogenic acid alpha-glucosidase (GAA) gene variants.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# NIKTIMVO

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## Products Affected

- NIKTIMVO

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	Graft-Versus-Host Disease (all of A, B, and C): A. Patient is greater than or equal to 40 kg, AND B. Patient has chronic graft-versus-host disease, AND C. Patient has tried at least two conventional systemic treatments for chronic graft-versus-host disease. Note: Examples of systemic therapy may include ruxolitinib tablets, belumosudil tablets, ibrutinib tablets, capsules, and oral suspension.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# NILUTAMIDE

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## 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 dexamethasone and 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, Multiple myeloma after previous treatment (either monotherapy or in combination other than lenalidomide/dexamethasone) or stem cell transplant
Part B Prerequisite	Yes

# 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 biallelic pathogenic/likely pathogenic variants in the FAH gene OR elevated levels of succinylacetone in the serum or urine.
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	Diagnosis
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,Radiation-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)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), 2)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), 3)patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia

<b>PA Criteria</b>	<b>Criteria Details</b>
	[absolute neutrophil count less than 100 cells/mm <sup>3</sup> ], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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)
<b>Part B Prerequisite</b>	No

# NON-INJECTABLE TESTOSTERONE PRODUCTS

## Products Affected

- ANDROGEL TRANSDERMAL GEL IN METERED-DOSE PUMP
- 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
- UNDECATREX
- VOGELXO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.]
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	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

<b>PA Criteria</b>	<b>Criteria Details</b>
	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).
<b>Part B Prerequisite</b>	No

# NOURIANZ

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## 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	1 year
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 Promacta. A trial of Alvaiz would also count. 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Thrombocytopenia, Chemotherapy-Induced and Thrombocytopenia in Myelodysplastic Syndrome

PA Criteria	Criteria Details
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) analog (See Note 1) or if the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration sensitive-approve if the medication will be used in combination with a GnRH analog (See Note 1) or if the patient had a bilateral orchiectomy. Note 1: examples of GnRH analogs 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 subcutaneous injection), Orgovyx (relugolix tablets).
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
<b>Exclusion Criteria</b>	Concurrent use with another monoclonal antibody therapy.
<b>Required Medical Information</b>	COPD initial - Approve if pt meets all (A, B AND C): A) pt has a blood eosinophil level at least 300 cells per microliter within the previous 6 weeks or prior to treatment with Nucala or another monoclonal antibody therapy that may alter blood eosinophil levels AND B) received at least 3 months of combination therapy with at least two of LAMA, LABA or ICS, AND C) pt meets (i or ii): i) experienced two or more COPD exacerbations requiring treatment with a systemic corticosteroid with or without an antibiotic in the previous 12 months OR ii) experienced one or more COPD exacerbations requiring a hospitalization in the previous 12 months. Cont - Approve if pt meets all (A, B and C): A) has already received at least 6 months of therapy with Nucala AND B) continues to receive combination therapy with an inhaled LABA and LAMA AND C) patient has experienced a beneficial clinical response, defined by one of the following: reduced symptoms, exacerbations, hospitalizations, ED/urgent care visits, improved lung function).
<b>Age Restrictions</b>	(Initial therapy only): Asthma-6 years of age and older. EGPA/Polyps/COPD-18 years of age and older. HES-12 years and older.
<b>Prescriber Restrictions</b>	(Initial therapy only): Asthma/COPD-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
<b>Coverage Duration</b>	Initial-Asthma/polyps/COPD-6 months, EGPA/HES-8 months. 12 months continuation.
<b>Other Criteria</b>	Asthma initial - must have blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks (or prior to tx with Nucala or another monoclonal antibody therapy that may lower blood eosinophil levels) AND has received combo tx w/inhaled corticosteroid

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

# NUEDEXTA

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## Products Affected

- NUEDEXTA

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 a neurologist
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	1 year if genetic testing confirmed diagnosis. 1 month if genetic testing is in progress.
Other Criteria	Molybdenum Cofactor Deficiency (MoCD) Type A-approve if the patient has genetic testing confirmation of biallelic pathogenic or likely pathogenic variants in the MOCS1 gene or if the patient has laboratory findings suggestive of molybdenum cofactor deficiency (MoCD) and genetic testing is in progress. (Note: Laboratory findings include elevated urinary S-sulfocysteine, thiosulfate, xanthine, hypoxanthine, or decreased serum uric acid.)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# NUPLAZID

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## 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
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Migraine, Acute treatment (initial and continuation)-approve. Preventive treatment of episodic migraine (initial)-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). Preventive treatment of episodic migraine (continuation) - 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 the patient has had a significant clinical benefit from the medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NYPOZI

## Products Affected

- NYPOZI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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-6mo.HIV/AIDS-4 mo.MDS-3mo.PBPC, agran/neutropenia, ALL,BMT-1mo.Radiation-1 mo.
Other Criteria	CANCER PATIENTS RECEIVING CHEMOTHERAPY - ONE of (A, B, C, or D): A) receiving myelosuppressive anti-cancer medications associated with a high risk of febrile neutropenia (risk at least 20% based on the chemotherapy regimen), OR B) receiving myelosuppressive anti-cancer medications associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and 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) had neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim, pegfilgrastim) and a reduced dose or frequency of chemotherapy may compromise treatment, OR D) has received chemotherapy and has febrile neutropenia with at least one risk factor for poor clinical outcomes or for developing infection-associated complications (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm3],

PA Criteria	Criteria Details
	<p>neutropenia expected to be greater than 10 days in duration, invasive fungal infection, hospitalization at the time of fever, prior episode of febrile neutropenia). FOR ALL DIAGNOSIS EXCEPT PBPC AND RADIATION SYNDROME - In addition to the criteria above, ONE of (A or B): A) tried Releuko and Nivestym and cannot continue to use due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction, OR B) patient initiated therapy with Nypozi and requires additional medication to complete the current cycle of chemotherapy. FOR PBPC - In addition to criteria above, ONE of (A or B): A) tried Nivestym and cannot continue to use due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction, OR B) patient initiated therapy with Nypozi and requires additional medication to complete the current cycle of chemotherapy.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Neutropenia associated with HIV or AIDS. Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Acute lymphocytic leukemia (ALL).
<b>Part B Prerequisite</b>	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-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 meets one of the following: 1) 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), 2) 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 3) patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No

# OCREVUS

## Products Affected

- OCREVUS
- OCREVUS ZUNOVO

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-prescr/consult with oncologist. Diarrhea assoc w chemo-prescr/consult with oncologist/gastro. Small bowel bleed/angiodysplasia-prescr/consult gastroenterologist.
Coverage Duration	Enterocutaneous fistula/diarrhea w/chemo-3 mos, other 1 yr
Other Criteria	ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender. DIARRHEA ASSOC W CHEMO (A and B): A) grade 3 or 4 diarrhea and B) patient has tried at least one antimotility medication. SMALL BOWEL BLEEDS/ANGIODYSPLASIA RELATED BLEEDING: pt has chronic, recurrent gastrointestinal bleeds lasting greater than or equal to 3 months.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma, enterocutaneous fistulas, diarrhea associated with chemotherapy, small bowel bleeds/angiodysplasia related bleeding

PA Criteria	Criteria Details
Part B Prerequisite	No

# ODACTRA

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## 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 5 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

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## 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.) Diffuse Basal Cell Carcinoma Formation, including basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Metastatic BCC, diffuse basal cell carcinoma formation
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	IDIOPATHIC PULMONARY FIBROSIS (IPF), INITIAL [A and B]: A) diagnosis confirmed by presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) or surgical lung biopsy and B) forced vital capacity (FVC) greater than or equal to 40 percent of the predicted value. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS, INITIAL (A and B): A) diagnosis confirmed by HRCT and B) FVC greater than or equal to 40 percent of the predicted value. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE, INITIAL (all of A, B and C): A) FVC greater than or equal to 45 percent of the predicted value, B) fibrosing lung disease impacting more than 10 percent of lung volume on HRCT, and C) clinical signs of progression. ALL INDICATIONS, CONTINUATION: approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# OGSIVEO

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## Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 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	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



# OHTUVAYRE

## Products Affected

- OHTUVAYRE

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	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) - trial of one preferred Long-Acting Muscarinic Antagonist (LAMA) product AND one preferred Long-Acting Beta-Agonist (LABA) product. (A trial of a non-preferred LAMA or LABA will also count. A combination LAMA/LABA product will count for both requirements. An inhaled corticosteroid [ICS]/LABA product will count towards trial of a LABA.) Preferred products: Bevespi Aerosphere (LAMA/LABA), Stiolto Respimat (LAMA/LABA), tiotropium bromide (LAMA), Spiriva Respimat (LAMA), Striverdi Respimat (LABA), fluticasone-salmeterol diskus (ICS/LABA), budesonide-formoterol (ICS/LABA), Breo Ellipta (ICS/LABA).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# OJEMDA

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## Products Affected

- OJEMDA ORAL SUSPENSION FOR RECONSTITUTION MG/WEEK (100 MG X 5), 600 MG/WEEK (100 MG X 6)
- OJEMDA ORAL TABLET 400 MG/WEEK (100 MG X 4), 500

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	6 months of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	PEDIATRIC LOW GRADE GLIOMA-patient has relapsed or refractory disease and the tumor is positive for one of the following: BRAF fusion, BRAF rearrangement or BRAF V600 mutation.
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 (A, B or C): A) intermediate-risk or high-risk disease, or B) lower-risk disease and has one disease-related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis), or C) myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease- related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Accelerated or blast phase myeloproliferative neoplasm
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
<b>Exclusion Criteria</b>	Concurrent use with a biologic, biologic immunomodulators, topical Janus Kinase Inhibitors (JAKis), targeted synthetic DMARDs, or other potent immunosuppressants. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).
<b>Required Medical Information</b>	Diagnosis, previous medication use, concurrent medication
<b>Age Restrictions</b>	Alopecia areata-18 years and older (initial/cont).All other dx-18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	RA-Prescribed by or in consultation with a rheumatologist (initial therapy). Alopecia Areata-prescribed by or in consultation with a dermatologist (initial/cont).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	Initial therapy, RA - approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, 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.] 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 if the prescriber states the patient continues to require systemic therapy for the treatment of alopecia areata. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# OMVOH IV

## Products Affected

- OMVOH INTRAVENOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	3 doses for induction
<b>Other Criteria</b>	<p>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: a preferred ustekinumab product, Entyvio IV, a preferred infliximab product, Skyrizi, Tremfya, Rinvoq or a preferred adalimumab product. Trial(s) of a Non-Preferred infliximab product, Simponi SC, Entyvio SC, a non-preferred ustekinumab product or a Non-Preferred adalimumab product will also count. Crohn's disease-</p> <p>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: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Entyvio IV, Rinvoq, Skyrizi, Tremfya. Trials of a non-preferred infliximab product, a non-preferred adalimumab, or a non-preferred ustekinumab product will also count. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred infliximab products include Remicade, Zymfentra. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No



# OMVOH SC

## Products Affected

- OMVOH PEN SUBCUTANEOUS PEN INJECTOR 100 MG/ML, 200 MG/2 ML (100 MG/ML X 2), 300MG/3ML(100MG /ML-200 MG/2ML)
- OMVOH SUBCUTANEOUS SYRINGE 100 MG/ML, 200 MG/2 ML (100 MG/ML X 2), 300MG/3ML(100MG /ML-200 MG/2ML)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years of age and older (initial)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist (initial therapy only)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	<p>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: a preferred ustekinumab product, Entyvio IV, Skyrizi, Tremfya, Rinvoq, a preferred infliximab product, or a preferred adalimumab product. Trial(s) of a Non-Preferred infliximab product, Simponi SC, Entyvio SC, a non-preferred ustekinumab product or a Non-Preferred adalimumab product will also count. Ulcerative colitis, continuation-approve if the patient has had a response. Crohn's disease, 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: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Entyvio IV, Rinvoq, Skyrizi, Tremfya. Trials of a Non-Preferred infliximab product, a non-preferred adalimumab, or a non-preferred ustekinumab product will also count. Crohn's disease, continuation-approve if the patient has had a response. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred infliximab</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	products include Remicade, Zymfentra. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ONAPGO

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## Products Affected

- ONAPGO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a serotonin 5-HT <sub>3</sub> antagonist
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- All of the following (A, B, C and D): A. Diagnosed with advanced Parkinson's disease, AND B. Experiencing off episodes, Note: Examples of off episodes include muscle stiffness, slow movements, or difficulty starting movements. AND C. Tried an oral carbidopa/levodopa therapy and had significant intolerance or inadequate efficacy, AND D. Previously tried or is currently receiving ONE other treatment for off episodes Note: Examples of treatment for off episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, opicapone capsules, or safinamide tablets.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ONGENTYS

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## 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 and if the patient has tried an entacapone product and had significant intolerance or inadequate efficacy 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
<b>Exclusion Criteria</b>	Concomitant use with Amvuttra (vutrisiran subcutaneous injection), Tegsedi (inotersen subcutaneous injection), Wainua (eplontersen subcutaneous injection), or a tafamidis product
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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]).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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 allogeneic hematopoietic stem cell transplant is not planned. Peripheral T-cell lymphoma - all of (A, B, and C): A) relapsed or refractory disease, and B) pt has one of the following (i, ii or iii): i) angioimmunoblastic T-cell lymphoma, or ii) nodal peripheral T-cell lymphoma with T-follicular helper (TFH) phenotype, or iii) follicular T-cell lymphoma, and C) medication is used as a single agent.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Peripheral T-cell lymphoma
Part B Prerequisite	No

# OPDIVO

## Products Affected

- OPDIVO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	colon/rectal/melanoma-12 years and older, pediatric hodgkin lymphoma-less than 18 years old, All other (except gestational trophoblastic and Kaposi sarcoma)-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, chronic lymphocytic leukemia/small lymphocytic lymphoma, pancreatic cancer, squamous cell skin carcinoma, thyroid carcinoma, vaginal cancer
Part B Prerequisite	No

# OPDIVO QVANTIG

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## Products Affected

- OPDIVO QVANTIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (all diagnoses except gestational trophoblastic neoplasia, Kaposi sarcoma)
Prescriber Restrictions	Prescribed by or on 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	appendiceal cancer, ampullary adenocarcinoma, anal carcinoma, biliary tract cancers, cervical cancer, endometrial carcinoma, gestational trophoblastic neoplasia, Kaposi sarcoma, merkel cell carcinoma, mesothelioma, neuroendocrine tumors, small bowel adenocarcinoma, small cell lung cancer, squamous cell skin carcinoma, thyroid carcinoma, vaginal cancer
Part B Prerequisite	No



# OPDUALAG

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## 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	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. Melanoma-approve if the patient is greater than or equal to 40 kg and either (i or ii): (i) the patient has unresectable or metastatic disease or (ii) medication is used as neoadjuvant therapy.
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 biallelic pathogenic or likely pathogenic acid alpha-glucosidase (GAA) gene variants.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# OPSUMIT

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## 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

# OPSYNVI

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## Products Affected

- OPSYNVI

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with guanylate cyclase stimulators
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1-approve if patient has had a right-heart catheterization to confirm the diagnosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# OPZELURA

## Products Affected

- OPZELURA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with other JAK inhibitors. Concurrent use with other potent immunosuppressants
<b>Required Medical Information</b>	Diagnosis, other medications tried
<b>Age Restrictions</b>	Atopic dermatitis- 2 years and older. Vitiligo-12 years and older
<b>Prescriber Restrictions</b>	AD-Prescribed by or in consultation with an allergist, immunologist or dermatologist. Vitiligo-prescribed by or in consultation with a dermatologist.
<b>Coverage Duration</b>	AD-8 weeks, vitiligo-6 months
<b>Other Criteria</b>	Atopic Dermatitis, mild to moderate- Approve if the patient meets all of the following (A, B, and C): 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 (1 or 2): 1) 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 OR 2) 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 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

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

# ORENCIA

## Products Affected

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SYRINGE 125 MG/ML, 50 MG/0.4 ML, 87.5 MG/0.7 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	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-approve. Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)]-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. Cont tx - responded to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ORENCIA IV

## Products Affected

- ORENCIA (WITH MALTOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	GVHD-2 years and other
<b>Prescriber Restrictions</b>	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. GVHD-prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	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-approve. Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)]-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. Cont tx - responded to therapy. GVHD-approve if Orencia is being used for prevention of acute graft-versus host disease, patient will also receive a calcineurin inhibitor for prevention of acute graft-versus-host disease, patient will also receive methotrexate for prevention of acute graft-versus-host disease, patient will undergo hematopoietic stem cell transplantation from one of the following donors: matched unrelated donor OR 1-allele-mismatched unrelated donor.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



PA Criteria	Criteria Details
Part B Prerequisite	No

# ORENITRAM

## Products Affected

- ORENITRAM MONTH 1 TITRATION KT
- ORENITRAM MONTH 2 TITRATION KT
- ORENITRAM MONTH 3 TITRATION KT
- ORENITRAM ORAL TABLET EXTENDED RELEASE 0.125 MG, 0.25 MG, 1 MG, 2.5 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.
<b>Required Medical Information</b>	Diagnosis, results of right heart cath
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH must be prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ORGOVYX

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## 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	1 year
Other Criteria	Prostate Cancer-approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ORIAHNN

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## 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 - Approve if the pt meets A, B and C: A) pt has two copies of the F508del mutation in the CFTR gene, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ORLADEYO

## Products Affected

- ORLADEYO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant Use with Other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda, Takhzyro).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older (initial and continuation)
<b>Prescriber Restrictions</b>	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)
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ORSERDU

## Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

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

# OTEZLA

## Products Affected

- OTEZLA MG (51), 10 MG (4)-20 MG (4)-30 MG (47)
- OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)- 20
- OTEZLA XR
- OTEZLA XR INITIATION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD).
<b>Required Medical Information</b>	Diagnosis, previous drugs tried
<b>Age Restrictions</b>	PP/PsA- 6 years and older (initial), All other dx - 18 years and older (initial)
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A, B or C]: A) tried at least one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial with a biologic also counts) or B) contraindication to MTX or C) patient has mild to moderate disease and the patient requires systemic therapy. PSORIATIC ARTHRITIS (PsA): approve. BEHCET'S-oral ulcers or other mucocutaneous involvement. CONTINUATION THERAPY (PP/PsA/Behcet's): received 4 months of therapy and had a response.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# OXERVATE

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## 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	Concurrent use with Rivfloza (nedosiran subcutaneous injection)
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	<p>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 0.5 mmol/24 hours/1.73 meters<sup>2</sup> 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).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# PADCEV

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## 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 (4-17 YRS)
- 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 1 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, C, and D: A) pt meets (i or ii): i) positive skin prick test response to peanut or ii) positive in vitro test (i.e., a blood test) for immunoglobulin E (IgE) to peanut, and B) this will be used in conjunction with a peanut-avoidant diet, and C) pt does NOT have uncontrolled asthma and D) patient has a history of an allergic reaction to peanut that met each of the following (i, ii, and iii): i. Signs and symptoms of a significant systemic allergic reaction, Note: Signs and symptoms of a significant systemic allergic reaction include hives, swelling, wheezing, hypotension, and gastrointestinal symptoms. AND, ii. Reaction occurred within a short period of time following a known ingestion of peanut or peanut-containing food, AND iii. Prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector. Note: Examples of epinephrine auto-injectors include EpiPen, EpiPen Jr., Auvi-Q, and generic epinephrine auto-injectors.
Indications	All FDA-approved Indications.

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

# PALYNZIQ

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## 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

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## 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



# PAVBLU

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## Products Affected

- PAVBLU

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

# PEMAZYRE

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

# PHENYL BUTYRATE

## Products Affected

- BUPHENYL
- *glycerol phenylbutyrate*
- PHEBURANE
- RAVICTI
- *sodium phenylbutyrate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant therapy with more than one phenylbutyrate product
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
<b>Coverage Duration</b>	Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval
<b>Other Criteria</b>	Urea cycle disorders-approve if genetic or enzymatic testing confirmed 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# PHOSPHATE BINDERS AND SIMILAR AGENTS

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## Products Affected

- AURYXIA
- *calcium acetate(phosphat bind)*
- FERRIC CITRATE
- FOSRENOL
- *lanthanum*
- RENVELA
- *sevelamer carbonate*
- *sevelamer hcl*
- VELPHORO
- XPHOZAH

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients on dialysis [non-D use]. For Auryxia when used for the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis [non-D use]
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

## Products Affected

- ADCIRCA
- *alyq*
- REVATIO ORAL TABLET
- *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



# PIASKY

## Products Affected

- PIASKY

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another complement inhibitor
Required Medical Information	Diagnosis
Age Restrictions	13 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with a hematologist (initial/continuation)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	INITIAL THERAPY: PAROXYSMAL NOCTURNAL HEMOGLOBINURIA- confirmed by peripheral blood flow cytometry with results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages AND weight is at least 40 kg. CONTINUATION: continuing to derive benefit from PiaSky. Note: Examples of benefit include increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis. Note: A patient who has not started maintenance therapy with PiaSky subcutaneous should be considered under initial therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# PIQRAY

## Products Affected

- PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X 1), 300 MG/DAY (150 MG X 2)

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.
Off-Label Uses	N/A
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 (initial therapy)- 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. IPF (continuation of therapy)-approve. For both initial therapy and continuation of therapy- 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

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## 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
<b>Exclusion Criteria</b>	Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS).
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist or an MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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. Note: Diffuse large B-cell lymphoma includes histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma. B-Cell Lymphoma (Examples include HIV-related B-cell lymphoma and post-transplant lymphoproliferative disorders) - 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 biallelic pathogenic or likely pathogenic acid alpha-glucosidase (GAA) gene variants.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# PONVORY

## Products Affected

- PONVORY
- PONVORY 14-DAY STARTER PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# POSACONAZOLE (ORAL)

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## Products Affected

- NOXAFIL ORAL SUSP,DELAYED RELEASE FOR RECON
- NOXAFIL ORAL SUSPENSION
- *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 prophylaxis, 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

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## 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 ORAL CAPSULE
- PRADAXA ORAL PELLETS IN PACKET 110 MG, 150 MG, 20 MG, 30 MG, 40 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior medication history (all as described in Other Criteria field)
<b>Age Restrictions</b>	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
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	A fib/flutter/DVT/PE tx/reduce risk of recurr-1 yr,DVT/PE prophy(hip)/DVT prophy(knee)-60days.
<b>Other Criteria</b>	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. Approve Pradaxa Pellets if the patient has a diagnosis of venous

<b>PA Criteria</b>	<b>Criteria Details</b>
	thromboembolic events, treatment or venous thromboembolic events, to reduce the risk of recurrence.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Deep Vein Thrombosis in patients undergoing knee replacement surgery, prophylaxis
<b>Part B Prerequisite</b>	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	HeFH - 8 years and older. All other - 18 years of age and older.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL (or 155 mg/dL if less than 16 years old), b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD, HeFH, or HoFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. HYPERLIPIDEMIA WITH HoFH (both A and B): A) meets (a or b): a) phenotypic confirmation of HoFH, or b) meets (i and ii): i) untreated LDL-C greater than 400 mg/dL or treated LDL-C greater than or equal to 300 mg/dL, and ii) clinical manifestations of HoFH before 10 years of age or at least one parent with untreated LDL-C or total cholesterol consistent with FH, AND B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 70 mg/dL or higher or b) statin intolerant. FOR ALL INDICATIONS: must</p>

PA Criteria	Criteria Details
	<p>try Repatha prior to approval of Praluent, unless the request is for the treatment of HeFH in a patient less than 10 years old and greater than or equal to 8 years old. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PRETOMANID

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## 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

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## Products Affected

- PREVYMIS INTRAVENOUS
- PREVYMIS ORAL PELLETS IN PACKET 120 MG, 20 MG
- PREVYMIS ORAL TABLET

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

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## Products Affected

- BILDYOS
- CONEXXENCE
- JUBBONTI
- PROLIA
- STOBOCLO

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

# PROMACTA

## Products Affected

- *eltrombopag olamine*
- 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, prescribed by, or after consultation with, a hematologist (initial therapy). Hep C, 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). Post-transplant, prescribed by or in consult with a hematologist, oncologist or stem cell transplant specialist physician (initial)
Coverage Duration	ImmuneThrombo/MDS init3mo,cont1yr,AAinit4mo,cont1yr,Thrombo/HepC1yr,Transplant-init3mo,cont6mo
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 (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate, Tavalisse, Doptelet, rituximab) 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 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 microliter) AND tried one immunosuppressant therapy (e.g., cyclosporine) OR patient will be using Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS

<b>PA Criteria</b>	<b>Criteria Details</b>
	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. Thrombocytopenia post-allogeneic transplantation, initial - approve if, according to the prescriber, the patient has poor graft function AND has a platelet count less than 50,000/mcL. Cont- patient demonstrated a beneficial clinical response.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Thrombocytopenia in Myelodysplastic Syndrome (MDS), Thrombocytopenia in a patient post-allogeneic transplantation
<b>Part B Prerequisite</b>	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	<p>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.</p> <p>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 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.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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

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## Products Affected

- QULIPTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Migraine headache prevention-approve if the patient meets (A and B): A) has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication, and B) if the pt is currently taking Qulipta, the pt has had significant clinical benefit.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RADICAVA

## Products Affected

- EDARAVONE
- RADICAVA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	ALSFRS-R score
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 adequate respiratory function according to the prescriber, AND 4. 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.
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
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 adequate respiratory function according to the prescriber, AND 4. 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
Part B Prerequisite	No

# REBIF

## Products Affected

- REBIF (WITH ALBUMIN) MCG/0.5 ML, 8.8MCG/0.2ML-22
- REBIF REBIDOSE SUBCUTANEOUS MCG/0.5ML (6)
- PEN INJECTOR 22 MCG/0.5 ML, 44
- REBIF TITRATION PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agent used for multiple sclerosis
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or after consultation with a neurologist or an MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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	Transfusion Dependent Beta-Thalassemia-initial therapy-approve if according to the prescriber, the patient requires regular red blood cell transfusion and the patient has not received a gene therapy for transfusion-dependent beta-thalassemia (ex: Zynteglo, Casgevy) 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 a gene therapy for transfusion-dependent beta-thalassemia (ex: Zynteglo, Casgevy) 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. Myelodysplastic/myeloproliferative neoplasm-approve if the patient has myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis-associated anemia

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

# REBYOTA

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## Products Affected

- REBYOTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	30 days
Other Criteria	Prevention of recurrence of clostridioides difficile infection (CDI)-approve if the patient will complete their antibiotic treatment for recurrent CDI 24-72 hours before treatment with Rebyota and Rebyota will not be used for the TREATMENT of CDI.
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
<b>Exclusion Criteria</b>	Concurrent Use with Other Medications for Osteoporosis (e.g., other bisphosphonates, Evenity, Prolia, Forteo/Bonsity, Tymlos, calcitonin nasal spray)
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Paget's 1 month. Others 12 months.
<b>Other Criteria</b>	Tx of osteo in post menopausal pt or osteo in men (a man defined as an individual with biological traits of man, regardless of the individual's gender identity/gender expression), must meet ONE of the following: pt had inadequate response after 12 mo (eg, ongoing and sign loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or pt experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot swallow or has difficulty swallowing or pt cannot remain in upright position post oral bisphos admin or pt has pre-existing GI condition (eg, pt with esophageal lesions/ulcers, or abnormal of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt had an osteo fracture or a fragility fracture OR pt has tried IV Reclast (zoledronic acid). Tx of PMO may have also tried IV Boniva (ibandronate) for approval. Prevent or tx of GIO, approve if: pt is initiating or cont therapy with systemic glucocorticoids, AND had an inadequate response after 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had an osteo fracture or fragility fracture while on therapy or pt experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot

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

# RECORLEV

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## 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, and the patient has tried ketoconazole tablets, and the patient meets (i, ii or iii): i) the patient is not a candidate for surgery or surgery has not been curative, or ii) patient is awaiting surgery for endogenous Cushing's Syndrome, or iii) patient is awaiting therapeutic response after radiotherapy for endogenous Cushing's Syndrome.
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	Diagnosis
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,Radi-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)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), 2)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, priorchemotherapy 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), 3)patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgramstim products, pegfilgrastim products and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy, has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia

<b>PA Criteria</b>	<b>Criteria Details</b>
	[absolute neutrophil count less than 100 cells/mm <sup>3</sup> ], neutropenia expected to be greater than 10 days in duration, invasive fungal infection)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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), peripheral blood progenitor cell transplantation in patients with cancer
<b>Part B Prerequisite</b>	No

# REMICADE

## Products Affected

- INFLIXIMAB
- REMICADE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medication, previous medications tried
<b>Age Restrictions</b>	CD and UC, Pts aged 6 years or more (initial therapy). PP-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	FDAind ini-3 mo,cont1yr,GVHD ini-1 mo,cont-3 mo,Pyo Gang-ini4 mo,cont1 yr,others-ini 3mo,cont-12 mo
<b>Other Criteria</b>	INITIAL THERAPY: RHEUMATOID ARTHRITIS: tried one conventional synthetic DMARD for at least 3 months (e.g., MTX, leflunomide, hydroxychloroquine, sulfasalazine. 3-month trial of a biologic also counts). CROHN'S DISEASE: approve. ULCERATIVE COLITIS: approve. BEHCET'S (A or B): A) tried one conventional therapy (e.g., systemic CS, immunosuppressants such as AZA, MTX, mycophenolate, CSA, tacrolimus, chlorambucil, cyclophosphamide, interferon alfa. TNF inhibitor also counts.) or B) ophthalmic manifestations. STILL'S DISEASE (A and B): A) tried one CS and B) tried one DMARD for at least 2 months or intolerant (e.g., MTX. Trial of a biologic also counts.) UVEITIS: tried periocular, intraocular or systemic CS or immunosuppressive (e.g., MTX, mycophenolate, CSA. Trial of a biologic also counts.) SARCOIDOSIS (A and B): A) tried one CS and B) tried one immunosuppressant (e.g., MTX, AZA, leflunomide, mycophenolate, hydroxychloroquine, chloroquine.) PYODERMA GANGRENOSUM (A or B): A) tried one systemic CS or B) tried one immunosuppressant for at least 2 months or intolerant (e.g.,

PA Criteria	Criteria Details
	<p>mycophenolate, CSA). HIDRADENITIS SUPPURATIVA: Tried one other therapy (e.g., intralesional or oral CS, systemic antibiotics, isotretinoin). GRAFT VS HOST DISEASE: Tried one conventional systemic treatment (e.g., CS, antithymocyte globulin, CSA, tacrolimus, mycophenolate.) JUVENILE IDIOPATHIC ARTHRITIS: (A or B): A) tried one systemic medication (e.g., MTX, sulfasalazine, leflunomide, NSAID. Trial of a biologic also counts.) or B) has aggressive disease. PLAQUE PSORIASIS (A or B): A) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Trial of a biologic will also count) or B) contraindication to MTX. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. ALL DX: Requests for infliximab must try Remicade first.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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
<b>Part B Prerequisite</b>	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	<p>Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Pulmonary Arterial Hypertension (PAH) [World Health Organization (WHO) Group 1], Initial Therapy- Approve if the patient meets all of the following criteria (i, ii, iii, and iv): i. Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH), AND ii. Patient meets the following criteria (a and b): a) Patient has had a right heart catheterization, AND b) Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH, AND iii. Patient meets ONE of the following criteria (a or b): a) Patient is in Functional Class III or IV, OR b) Patient is in Functional Class II and meets ONE of the following criteria [(1) or (2)]: (1) Patient has tried or is currently receiving one oral agent for PAH, OR (2) Patient has tried one inhaled or parenteral prostacyclin product for PAH, AND iv. Patient with idiopathic PAH must meet ONE of the following criteria (a, b, c, d, or e): a) Patient meets both of the following criteria [(1) and (2)]: (1) the patient has had an acute response to vasodilator testing that occurred during the right heart catheterization, AND (2) Patient has tried one calcium channel blocker (CCB) therapy, OR b) According to the prescriber, the patient did not have an acute response to vasodilator testing, OR c) 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</p>

PA Criteria	Criteria Details
	<p>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 for subcutaneous continuous infusion must meet (A, B or C): (A): tried 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 would result in a significant allergy or serious adverse reaction, (B): 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 or (C): has been stabilized on brand name product for 90 days or more. Patients requesting brand name Remodulin for intravenous continuous infusion must have tried 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 would result in a significant allergy or serious adverse reaction.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RENFLEXIS

## Products Affected

- RENFLEXIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medication, medications previously tried
<b>Age Restrictions</b>	CD/UC - Pts aged 6 years or more (initial therapy). PP-Pts aged 18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	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), Behcet's Disease- rheum, derm, ophthalmologist, gastro, or neurologist (initial therapy), Sarcoidosis-pulmonol, ophthalmol, cardio, neuro or dermatol (initial therapy)
<b>Coverage Duration</b>	FDAind ini-3 mo,cont1yr,GVHD ini-1 mo,cont-3 mo,Pyo Gang-ini4 mo,cont1 yr,others-ini 3mo,cont-12 mo
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Behcet's disease, Still's disease, Uveitis, Pyoderma gangrenosum, Hidradenitis suppurativa, Graft-versus-host disease, Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis
<b>Part B Prerequisite</b>	No

# REPATHA

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## Products Affected

- REPATHA
- REPATHA SURECLICK
- REPATHA PUSHTRONEX

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	N/A
Coverage Duration	Approve for 1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No



# RETEVMO

## Products Affected

- RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors-2 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 or RET pathogenic variant AND the patient meets i, ii or iii: i. patient has anaplastic thyroid cancer OR ii. the disease requires treatment with systemic therapy and patient has medullary thyroid cancer or iii. the disease requires treatment with systemic therapy and the disease is radioactive iodine-refractory if radioactive iodine is appropriate. 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
Part B Prerequisite	No

# REVCOVI

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## 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

# REVUFORJ

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## Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	ACUTE LEUKEMIA-patient has relapsed or refractory disease and the disease is positive for a lysine methyltransferase 2A (KMT2A) gene translocation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# REYVOW

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## 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

# REZDIFFRA

## Products Affected

- REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	<p>INITIAL THERAPY: METABOLIC-DYSFUNCTION ASSOCIATED STEATOHEPATITIS (MASH)/NON-ALCOHOLIC STEATOHEPATITIS (NASH) WITH MODERATE-ADVANCED LIVER FIBROSIS: All of (i, ii and iii): i) Diagnosed by (a or b): a) Liver biopsy performed within 3 years preceding treatment with Rezdiffra showing non-alcoholic fatty liver disease activity score of greater than or equal to 4 with a score of greater than or equal to 1 in ALL of the following: steatosis, ballooning and lobular inflammation, or b) One of the following within 6 months preceding treatment with Rezdiffra (1, 2 or 3): 1) Elastography (e.g. vibration-controlled transient elastography (e.g., FibroScan), transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography) or 2) Computed tomography or 3) Magnetic resonance imaging, and ii) stage F2 or F3 fibrosis prior to Rezdiffra and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber attestation the patient has received counseling on diet and exercise). CONTINUATION THERAPY (on therapy less than 1 year or restarting, review as initial therapy):</p> <p>MASH/NASH: All of (i, ii and iii): i) completed greater than or equal to 1 year of therapy and has not had worsening of fibrosis or MASH/NASH, and ii) has not progressed to stage F4 (cirrhosis) and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber attestation the patient has received counseling on diet and exercise).</p>

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

# REZLIDHIA

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## 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

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## 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

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## 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

- *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
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	PsA/JIA - 2 years and older (initial therapy), RA/UC/AS/CD/nr-axSpA/GCA-18 years and older (initial therapy), AD-12 years and older (initial therapy)
<b>Prescriber Restrictions</b>	RA/AS/Non-Radiographic Spondy/JIA/GCA, 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. (all apply to initial therapy only)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA)/PSORIATIC ARTHRITIS (PsA)/ULCERATIVE COLITIS (UC)/ANKYLOSING SPONDYLITIS (AS)/CROHN'S DISEASE (CD)/ JUVENILE IDIOPATHIC ARTHRITIS (JIA): 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. ATOPIC DERMATITIS (AD): 90 day trial of at least one systemic therapy (e.g., Dupixent [dupilumab subcutaneous injection] and Adbry [tralokinumab-ldrm subcutaneous injection]. Azathioprine, cyclosporine, or mycophenolate mofetil also count.) or unable to tolerate a 90 day trial. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (A and B): A) objective signs of inflammation defined as having at least one of the following (a or b): a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI and B) 3-month trial of at least

<b>PA Criteria</b>	<b>Criteria Details</b>
	one TNFi or was unable to tolerate a 3-month trial. GIANT CELL ARTERITIS: tried or is currently taking one systemic corticosteroid or corticosteroids are contraindicated. CONTINUATION THERAPY: ALL INDICATIONS: patient responded to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RINVOQ LQ

## Products Affected

- RINVOQ LQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic DMARD, other potent immunosuppressants, other janus kinase inhibitors, or a biologic immunomodulator.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	PsA-2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	JIA-prescribed by or in consultation with a rheumatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or a dermatologist (initial therapy)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: JUVENILE IDIOPATHIC ARTHRITIS (JIA)/ PSORIATIC ARTHRITIS (PsA) - 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. CONTINUATION THERAPY: ALL INDICATIONS - patient responded to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RITUXAN

## Products Affected

- RITUXAN
- RITUXAN HYCELA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Rituximab will not be used concurrently with another biologic or with a targeted synthetic DMARD (RA diagnosis)-initial therapy
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA-prescribed by or in consultation with a rheumatologist (initial therapy)
<b>Coverage Duration</b>	RA-1 month, all others-1 year
<b>Other Criteria</b>	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 polyangiitis and is greater than or equal to 2 years of age but less than 18.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RIVFLOZA

## Products Affected

- RIVFLOZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of Rivfloza with Oxlumio (lumasiran subcutaneous injection)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	2 years of age and older (initial)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist or urologist
<b>Coverage Duration</b>	Initial-6 months, continuation 1 year
<b>Other Criteria</b>	<p>Primary Hyperoxaluria Type 1, initial therapy-Approve if the patient meets the following (i, ii, iii and iv): 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 an estimated glomerular filtration rate (eGFR) greater than or equal to 30 ml/min per 1.73 m<sup>2</sup>, AND iii. Patient meets ONE of the following (a, b, or c): a) Patient has a urinary oxalate excretion greater than or equal to 0.5 mmol/24 hours/1.73 meters<sup>2</sup>, 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 iv. Patient has not previously received a liver transplant for Primary Hyperoxaluria Type 1. Primary Hyperoxaluria Type 1, continuation-Approve if the patient is continuing to derive benefit from Rivfloza as determined by the most recent (i.e., within the past 6 months) objective measurement. Note: Examples of objective measurements of a response to Rivfloza therapy are reduced urinary oxalate excretion, decreased urinary oxalate:creatinine ratio, or reduced plasma oxalate levels from baseline (i.e., prior to Rivfloza therapy) or improved or stabilized clinical signs/symptoms of Primary Hyperoxaluria Type 1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment).</p>
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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 meets one of the following: 1) 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), 2) 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 3) 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 Fulphila or Nyvepria prior to approval of Rolvedon.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ROMVIMZA

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## Products Affected

- ROMVIMZA

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)-tumor is not amenable to improvement with surgery.
Indications	All FDA-approved Indications.
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 and C): 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. Pancreatic adenocarcinoma-approve if pt has a BRCA mutation or PALB2 mutation AND pt has tried platinum-based chemotherapy AND has not had disease progression following the most recent platinum-based chemotherapy. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma
Part B Prerequisite	No

# RUFINAMIDE

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## 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

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## 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

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## 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 pt has locally advanced or metastatic disease AND either (A or B): (A) pt has epidermal growth factor receptor (EGFR) exon 20 insertion mutations, EGFR exon 19 deletion, or EGFR exon 21 L858R mutation, as detected by an approved test OR pt meets both of the following (a and b): a) medication is used as subsequent therapy AND b) pt has EGFR S768I, L861Q, and/or G719X mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No



# RYDAPT

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## 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

# 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	<p>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.</p> <p>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).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# RYSTIGGO

## Products Affected

- RYSTIGGO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, or a Rituximab Product.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Initial-6 months, Continuation-1 year
<b>Other Criteria</b>	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, 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, C) Patient received or is currently receiving pyridostigmine or has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine, 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), 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 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.
<b>Indications</b>	All FDA-approved Indications.

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

# RYTELO

## Products Affected

- RYTELO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist (initial)
Coverage Duration	1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. INITIAL THERAPY: MYELOYDYSPLASTIC SYNDROME-All of (i, ii, iii, iv, and v): i.Low- to intermediate-1 risk myelodysplastic syndrome (MDS), Note: MDS risk category is determined using the International Prognostic Scoring System (IPSS). AND, ii.Transfusion-dependent anemia, defined as requiring transfusion of greater than or equal to 4 red blood cell units over an 8-week period, AND iii. Has not responded, lost response to, or is ineligible for erythropoiesis-stimulating agents, Note: Examples of erythropoiesis-stimulating agents (ESA): epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera). AND, iv. Does NOT have deletion 5q [del(5q)] cytogenic abnormalities, AND v.Rytelo will NOT be used in combination with an ESA.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# RYZNEUTA

## Products Affected

- RYZNEUTA

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 or hematologist
Coverage Duration	6 months
Other Criteria	<p>Cancer in a patient receiving myelosuppressive chemotherapy-Approve if the patient meets ONE of the following (i, ii, or iii): i.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 ii. Patient meets both of the following (a and b): a) 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 b) Patient has at least ONE risk factor for febrile neutropenia according to the prescriber, Note: Examples of risk factors include age greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status, or human immunodeficiency virus (HIV) infection patients with low CD4 counts. OR iii. Patient meets both of the following (a and b): a) Patient had a neutropenic complication from the previous chemotherapy cycle and did NOT receive prophylaxis with a colony stimulating factor, AND b) A reduced dose or frequency of chemotherapy may compromise treatment outcome. Patients are required to try Nyvepria or Fulphila and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Ryzneuta.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SANDOSTATIN LAR

## Products Affected

- *octreotide,microspheres* SUSPENSION,EXTENDED REL
- SANDOSTATIN LAR DEPOT RECON
- INTRAMUSCULAR

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. Merkel cell/Thymoma/Thymic carcinoma-prescr/consult w/oncologist. Diarrhea assoc w chemo-prescr/consult oncologist/gastro. Small bowel bleed/angiodysplasia-prescr/consult gastroenterologist.
Coverage Duration	Enterocutaneous fistula/diarrhea chemo - 3 months, small bowel bleed - 6 mos, all others - 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). Diarrhea assoc w chemo (A and B): A) grade 3 or 4 diarrhea and B) patient has tried at least one antimotility medication. Merkel cell carcinoma (A and B): A) patient has regional or distant metastatic disease and B) has contraindications to or has progressed on checkpoint immunotherapy. 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. Small bowel bleeds/angiodysplasia related bleeding: pt has chronic, recurrent gastrointestinal bleeds lasting greater than or equal to 3 months.



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pheochromocytoma/paraganglioma, Meningioma, Thymoma and thymic carcinoma, enterocutaneous fistulas, diarrhea associated with chemotherapy, Merkel cell carcinoma, small bowel bleeds/angiodysplasia related bleeding
<b>Part B Prerequisite</b>	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
Part B Prerequisite	No

# SAPROPTERIN

## Products Affected

- *javygtor*
- KUVAN
- *sapropterin*
- *zelvysia*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Palynziq
<b>Required Medical Information</b>	Diagnosis, Phe concentration
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)
<b>Coverage Duration</b>	Initial-12 weeks, Continuation-1 year
<b>Other Criteria</b>	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 response to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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 pt meets (A, B, or C): A) the requested medication will be used as primary therapy in combination with (i or ii): i) bortezomib, lenalidomide, and dexamethasone, or ii) Kyprolis (carfilzomib intravenous infusion), lenalidomide, and dexamethasone, or B) 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, or C) medication will be used in combination with Kyprolis and dexamethasone and pt has tried at least one prior 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 100 MG, 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 or BCR::ABL1-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i, ii or iii): i. Patient has newly diagnosed disease, OR ii. The chronic myeloid leukemia is T315I-positive, OR iii. Patient has tried at least one other tyrosine kinase inhibitor. Note: Examples of tyrosine kinase inhibitors include imatinib, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), dasatinib, and 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

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## Products Affected

- SIGNIFOR

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

# SIGNIFOR LAR

## Products Affected

- SIGNIFOR LAR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly- Prescribed by or in consultation with an endocrinologist. Cushing's - Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy).
Coverage Duration	Acromegaly- 1 year. Cushing's disease/syndrome-Initial - 4 months, Continuation - 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. 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 meets i., ii, or iii.-i. 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. if the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). In addition for acromegaly, patients are required to try Somaultine Depot prior to approval of Signifor LAR.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No



# SILIQ

## Products Affected

- SILIQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Previous medication use
<b>Age Restrictions</b>	18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist (initial therapy)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	Initial therapy-Plaque Psoriasis-Approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya, Sotyktu. Continuation Therapy - approve if the patient had a response as determined by the prescriber. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	UC-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	<p>AS, initial -approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Xeljanz/XR, Cosentyx. Note: A previous trial of a nonpreferred adalimumab product would also count. PsA, initial-approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Cosentyx, Tremfya, a preferred ustekinumab product, Otezla, Orencia, Rinvoq, Skyrizi, Xeljanz/XR. Note: A previous trial of a nonpreferred adalimumab/ustekinumab product would also count. RA, initial- approve if the patient has tried two of the following drugs in the past: Enbrel, a preferred adalimumab product, Orencia, Rinvoq or Xeljanz/XR. Note: A previous trial of a nonpreferred adalimumab product would also count. Ulcerative colitis, initial - approve if the patient has had a trial with TWO of the following drugs: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Rinvoq, Tremfya, Skyrizi. Note: A previous trial of a nonpreferred adalimumab/infliximab/ustekinumab product would also count. Continuation tx - approve if the pt had a response as determined by the prescriber. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred infliximab</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	products include Remicade, Zymfentra. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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 end of plan year
Other Criteria	RA - Approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Orencia, a preferred infliximab product or Xeljanz/XR. (Note: if the patient has not tried TWO of these drugs listed, a previous trial with Cimzia, a non-preferred infliximab, Actemra, Kevzara, Kineret, a non-preferred adalimumab or Rituxan can count toward meeting the try TWO requirement.) PsA - Approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Cosentyx, Tremfya, a preferred ustekinumab product, Otezla, Orencia, Rinvoq, Skyrizi, Xeljanz/XR. (Note: if the patient has not tried TWO of these drugs listed, a previous trial with Cimzia, Taltz, a non-preferred adalimumab/ustekinumab or infliximab can count toward meeting the try TWO requirement.) AS-Approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Xeljanz/XR, Cosentyx (Note: if the patient has not tried TWO of these drugs listed, a previous trial with Cimzia, Taltz, a non-preferred adalimumab or infliximab can count toward meeting the try TWO requirement.) 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

<b>PA Criteria</b>	<b>Criteria Details</b>
	response to therapy as according to prescriber. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred infliximab products include Remicade. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SIRTURO

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## Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	Patients weighing less than 8 kg
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	Patients 2 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with an infectious diseases specialist or pulmonologist
Coverage Duration	9 months
Other Criteria	Tuberculosis (Pulmonary) -Approve if the patient has multidrug-resistant tuberculosis or Mycobacterium tuberculosis resistant to at least rifampin and isoniazid, 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	<p>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 size, immunoglobulin replacement therapy use, infection rate, or immunoglobulin M (IgM) levels.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No



# SKYRIZI

## Products Affected

- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE
- 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/UC-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/UC-presc/consult-gastro (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or PUVA) for at least 3 months, unless intolerant. (Note: a 3-month trial or previous intolerance to at least one biologic also counts) or B) contraindication to MTX. PSORIATIC ARTHRITIS (PsA): approve. CROHN'S DISEASE (CD):approve. UICERATIVE COLITIS (UC)-approve. CD/UC: Patient must be receiving induction dosing with Skyrizi IV within 3 months of initiating therapy with Skyrizi subcutaneous. CONTINUATION THERAPY: ALL INDICATIONS: patient has responded to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# SKYRIZI IV

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## Products Affected

- SKYRIZI INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis, Previous medication use
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	Approve for 3 doses
Other Criteria	Crohn's Disease- approve if this medication will be used as induction therapy. Ulcerative colitis- approve if this medication will be used as induction therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# SOFOSBUVIR/VELPATASVIR

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## Products Affected

- SOFOSBUVIR-VELPATASVIR

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

# SOHONOS

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## 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

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## 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

- BKEMV
- EPYSQLI
- SOLIRIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with a rituximab product, a Neonatal Fc Receptor Blocker, Enspryng (satralizumab-mwge subcutaneous [SC] injection), Fabhalta (iptacopan capsule), Ultomiris (ravulizumab-cwzy intravenous [IV] infusion or SC injection), Uplizna (inebilizumab-cdon IV infusion), or Zilbrysq (zilucoplan subcutaneous injection). Concomitant use with Empaveli for more than 4 weeks.
<b>Required Medical Information</b>	Diagnosis, previous therapies tried, test results
<b>Age Restrictions</b>	gMG- 6 years and older (initial/continuation). Neuromyelitis optica, PNH- 18 years and older (initial/continuation)
<b>Prescriber Restrictions</b>	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)
<b>Coverage Duration</b>	aHUS, neuromyelitis-1 year, gMG/PNH-initial 6 months, cont-1 year
<b>Other Criteria</b>	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) if patient is 18 years of age or older, 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

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

# SOMAVERT

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## 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 (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender.
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	<p>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, oncocytic) 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 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</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	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
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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
<b>Part B Prerequisite</b>	Yes

# SOTYKTU

## Products Affected

- SOTYKTU

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs). Concurrent use with other potent immunosuppressants, including methotrexate.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist (initial)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of a biologic will also count) or B) contraindication to MTX. CONTINUATION THERAPY: patient had a response to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SOVALDI

## Products Affected

- SOVALDI ORAL PELLETS IN PACKET 150 MG, 200 MG
- SOVALDI ORAL TABLET 200 MG, 400 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Genotype 1 and 4 -18 years or older, Genotype 2 and 3-3 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
<b>Coverage Duration</b>	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance (Note-For genotypes 5 and 6, coverage will be approved only when used in combination with other agents according to AASLD/IDSA guidelines). And, patients with genotype 1, 4, 5, or 6 must try TWO of the following: ledipasvir/sofosbuvir, velpatasvir/sofosbuvir, Mavyret, Vosevi, unless ledipasvir/sofosbuvir, velpatasvir/sofosbuvir, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype 2 or 3 must try TWO of the following: velpatasvir/sofosbuvir, Mavyret, Vosevi, unless velpatasvir/sofosbuvir, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance
<b>Part B Prerequisite</b>	No

# SPEVIGO IV

## Products Affected

- SPEVIGO INTRAVENOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with another biologic prescribed for treatment of generalized pustular psoriasis
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist
<b>Coverage Duration</b>	2 doses
<b>Other Criteria</b>	<p>Generalized pustular psoriasis flare-Approve if the patient meets the following criteria (A, B, C, and D): A) Patient weighs greater than or equal to 40 kilograms (kg), AND B) Patient is experiencing a flare of a moderate-to-severe intensity, AND C) Patient meets ONE of the following (i or ii): i.Patient is not currently receiving Spevigo subcutaneous and meets ALL of the following (a, b, c, and d): a.Patient has Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of greater than or equal to 3 points, AND Note: The Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score ranges from 0 (clear skin) to 4 (severe disease). b.Patient has a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation subscore of greater than or equal to 2 points, AND c. Patient has new or worsening pustules, AND d. Patient has erythema and pustules which affects greater than or equal to 5% of body surface area, AND ii.Patient is currently receiving Spevigo subcutaneous and meets BOTH of the following (a and b): a.Patient has had an increase in Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of greater than or equal to 2 points, AND b. Patient has Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation subscore of greater than or equal to 2 points, AND D) If patient has already received Spevigo intravenous, patient meets BOTH of the following (i and ii): i.Patient has not already received two doses of Spevigo intravenous for treatment of the current flare, AND ii.If</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	patient has previously received two doses of Spevigo intravenous, at least 12 weeks have elapsed since the last dose of Spevigo.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SPEVIGO SC

## Products Affected

- SPEVIGO SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with another biologic or disease modifying antirheumatic drugs (DMARD) prescribed for treatment of generalized pustular psoriasis.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older (initial)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist (initial therapy)
<b>Coverage Duration</b>	Initial-6 months, Continuation-1 year
<b>Other Criteria</b>	INITIAL THERAPY- GENERALIZED PUSTULAR PSORIASIS (GPP)- Weight greater than or equal to 40 kilograms (kg). CONTINUATION- GENERALIZED PUSTULAR PSORIASIS- both (i and ii): i) Established on therapy for at least 6 months, AND Note: A patient who has received less than 6 months of therapy or who is restarting therapy should be considered under criterion Initial Therapy. ii) Experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: reduction of generalized pustular psoriasis flares or an improvement in GPPGA score.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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 the patient has no history of psychosis or has a history of psychosis but the prescriber believes that the benefits of Spravato outweigh the risks, AND patient's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A



PA Criteria	Criteria Details
Part B Prerequisite	No

# SPRYCEL

## Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*
- PHYRAGO ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG
- 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 dasatinib 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/bone cancer/ 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 or BCR::ABL1-positive CML. For ALL, patient must have Ph-positive ALL or ABL-class translocation. For Bone Cancer-approve if patient has chondrosarcoma or chordoma. 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, bone cancer, melanoma cutaneous
Part B Prerequisite	No

# STELARA

## Products Affected

- OTULFI SUBCUTANEOUS SOLUTION
- OTULFI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- PYZCHIVA AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR 45 MG/0.5 ML, 90 MG/ML
- PYZCHIVA SUBCUTANEOUS SOLUTION
- PYZCHIVA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- SELARSDI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- STELARA SUBCUTANEOUS SOLUTION
- STELARA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- STEQEYMA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- USTEKINUMAB SUBCUTANEOUS SOLUTION
- USTEKINUMAB SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- USTEKINUMAB-AEKN SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- USTEKINUMAB-TTWE SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- WEZLANA SUBCUTANEOUS SOLUTION
- WEZLANA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- YESINTEK SUBCUTANEOUS SOLUTION
- YESINTEK SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	PP-6 years and older (initial therapy).
<b>Prescriber Restrictions</b>	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).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications.

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

# STELARA IV

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## Products Affected

- OTULFI INTRAVENOUS
- PYZCHIVA INTRAVENOUS
- SELARSDI INTRAVENOUS
- STELARA INTRAVENOUS
- STEQEYMA INTRAVENOUS
- USTEKINUMAB INTRAVENOUS
- USTEKINUMAB-TTWE INTRAVENOUS
- WEZLANA INTRAVENOUS
- YESINTEK INTRAVENOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	Approve a single dose
<b>Other Criteria</b>	INDUCTION THERAPY for USTEKINUMAB IV: UC: approve. Crohn's Disease: approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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-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 a physician who has expertise in treating acute radiation syndrome.
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 meets one of the following: 1) 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), 2) 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 3) 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 Fulphila and Nyvepria and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior

<b>PA Criteria</b>	<b>Criteria Details</b>
	to approval of Stimufend unless patient has a diagnosis of radiation syndrome.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients undergoing PBPC collection and therapy
<b>Part B Prerequisite</b>	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, (A or B): A) patient has previously been treated with (i and ii): i) imatinib or Ayvakit and ii) sunitinib or Sprycel, or B) medication is used as first-line therapy for succinate dehydrogenase (SDH)-deficient disease. 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. Bone Cancer-approve if the patient has relapsed/refractory or metastatic disease AND the patient has tried one systemic chemotherapy regimen AND pt has Ewing sarcoma or osteosarcoma. 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). CNS tumors (Glioblastoma or H3-mutated high-grade glioma)-approve if the patient has recurrent or progressive disease. Uterine sarcoma- (A and B): A) pt has recurrent, advanced, inoperable, or metastatic disease, and B) tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Soft tissue Sarcoma, Bone Cancer, CNS tumors (Glioblastoma/H3-mutated high-grade glioma), Appendiceal cancer, Uterine sarcoma
<b>Part B Prerequisite</b>	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 variants OR ii. Low baseline serum alkaline phosphatase activity OR iii. An elevated level of a tissue non-specific alkaline phosphatase substrate (i.e., serum pyridoxal 5'-phosphate, serum or urinary inorganic pyrophosphate, urinary phosphoethanolamine) AND B) Patient meets one of the following (i or ii): i. Patient currently has, or has a history of clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, premature tooth loss, muscle weakness, poor feeding, failure to thrive, respiratory problems, Vitamin B6-dependent seizures) OR ii. Patient has a family history (parent or sibling) of hypophosphatasia without current clinical manifestations of hypophosphatasia
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# SUCRAID

## Products Affected

- SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient 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 or normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein], c) Decreased maltase (normal reference: greater than 100 U/g protein), d) Decreased or 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.
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	<p>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 meets (A or B): A) has papillary or follicular thyroid carcinoma and the disease is refractory to radioactive iodine therapy or B) has oncocytic (formerly Hurthle cell) carcinoma. 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)- approve 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] between the Brand and the corresponding generic product which, would result in a significant allergy or serious adverse reaction.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), extraskeletal myxoid chondrosarcoma, differentiated (ie, papillary, follicular, and oncocytic carcinoma) 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.
<b>Part B Prerequisite</b>	No

# SUNOSI

## Products Affected

- SUNOSI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of Sunosi with an oxybate product and/or Wakix (pitolisant tablets)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Excessive daytime sleepiness associated with narcolepsy-prescribed by or in consultation with a sleep specialist physician or neurologist
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SYFOVRE

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## Products Affected

- SYFOVRE (PF)

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 (i or ii): (i) the patient has a best corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts or (ii) the patient has a best corrected visual acuity (BCVA) of 20/320 or better using the Snellen chart.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# SYMDEKO

## Products Affected

- SYMDEKO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with unknown CFTR gene mutations, Combination therapy with Orkambi, Kalydeco or Trikafta
<b>Required Medical Information</b>	Diagnosis, specific CFTR gene mutations
<b>Age Restrictions</b>	Six years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	CF - Approve if the pt meets A, B and C: A) pt has at least one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic or patient has TWO copies of the F508 del mutation, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# SYMLIN

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## 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

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## 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

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## 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

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## Products Affected

- CIALIS ORAL TABLET 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

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## 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
<b>Exclusion Criteria</b>	Concomitant use with Onpattro or Tegsedi or Wainua. Concurrent use of Vyndaqel and Vyndamax.
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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 positive disease and the medication will be taken in combination with Mekinist. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of 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 patient has BRAF V600 mutation-positive disease AND

PA Criteria	Criteria Details
	<p>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). Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Mekinist. Small bowel adenocarcinoma, approve if pt has BRAF V600E mutation-positive advanced or metastatic disease and this will be used with Mekinist AND (i or ii): i) this will be used as initial therapy and pt has received previous FOLFOX/CAPEOX therapy in the adjuvant setting within the past 12 months or has a contraindication, or (ii) this will be used as second-line and subsequent therapy.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Differentiated Thyroid Cancer, Biliary tract cancer, central nervous system cancer, histiocytic neoplasm, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, hairy cell leukemia, small bowel adenocarcinoma
<b>Part B Prerequisite</b>	No



# TAGRISO

## Products Affected

- TAGRISO

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	<p>NSCLC-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)- approve if the patient has advanced or metastatic disease, has EGFR mutation-positive NSCLC as detected by an approved test. Note- examples of 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 advanced or 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 ineligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test. NSCLC- Unresectable Stage III - approve if the patient has locally advanced, unresectable (stage III) disease AND EGFR exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an approved test AND not had disease progression during or following platinum-based chemoradiation therapy. (Note: Patients could have received concurrent or sequential chemoradiation therapy.)</p>
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
<b>Exclusion Criteria</b>	Concomitant use with other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda)
<b>Required Medical Information</b>	Diagnosis, lab values
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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).
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TALTZ

## Products Affected

- TALTZ AUTOINJECTOR
- TALTZ AUTOINJECTOR (2 PACK)
- TALTZ AUTOINJECTOR (3 PACK)
- TALTZ SYRINGE SUBCUTANEOUS SYRINGE 20 MG/0.25 ML, 40 MG/0.5 ML, 80 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis, Previous medication use
<b>Age Restrictions</b>	PP-6 years and older (initial therapy), all other dx-18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	PP, initial therapy - approve if pt has tried TWO of the following: Enbrel, a preferred adalimumab, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya, Sotyktu. PsA, initial therapy - approve if pt has tried TWO of the following: Enbrel, a preferred adalimumab, Skyrizi, a preferred ustekinumab product, Otezla, Orencia, Rinvoq, Cosentyx (IV or SC) or Tremfya. A trial of a non-preferred adalimumab, a non-preferred ustekinumab, Cimzia, infliximab, Simponi Aria/SC will also count. AS, initial therapy - approve if pt has tried TWO of the following: Enbrel, a preferred adalimumab, Rinvoq or Cosentyx (IV or SC). A trial of a non-preferred adalimumab, Cimzia, infliximab, Simponi Aria/SC will also count. Non-radiographic axial spondyloarthritis, initial therapy- approve if the patient has tried Cosentyx (IV or SC) or Rinvoq. For all covered indications for continuation of therapy, approve if the pt has responded to therapy. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.

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

# TALVEY

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## 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	<p>Primary Immunoglobulin A Nephropathy-A) Initial therapy-Approve if the patient meets the following criteria (i, ii, iii, and iv): i. The diagnosis has been confirmed by biopsy, AND ii. Patient is at high risk of disease progression, defined by meeting a and b: a) Patient meets ONE of the following: Proteinuria greater than or equal to 0.5 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 ONE of the following for greater than or equal to 90 days: Angiotensin converting enzyme inhibitor OR Angiotensin receptor blocker, AND iii. Patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73 m<sup>2</sup>, AND iv. Patient has not previously been treated with Tarpeyo Note: For a patient currently receiving Tarpeyo, review using Criterion B. B) Continuation of therapy-approve if the patient meets the following criteria (i, ii, and iii): i. The diagnosis has been confirmed by biopsy, AND ii. Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for greater than or equal to 90 days: Angiotensin converting enzyme inhibitor OR Angiotensin receptor blocker, AND iii. Patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73 m<sup>2</sup>.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A



PA Criteria	Criteria Details
Part B Prerequisite	No

# TASIGNA

## Products Affected

- *nilotinib hcl oral capsule 150 mg, 200 mg, 50 mg*
- TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older, ALL - 15 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Acute lymphoblastic leukemia, philadelphia chromosome positive-approve. CML, philadelphia chromosome positive or BCR::ABL1-mutation positive chronic myeloid leukemia- approve. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafenib 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 Romvimza or cannot take Turalio or Romvimza, 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST), Pigmented villonodular synovitis/tenosynovial giant cell tumor, Myeloid/Lymphoid neoplasms with Eosinophilia, melanoma cutaneous.

PA Criteria	Criteria Details
Part B Prerequisite	No

# TAVALISSE

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## 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 Promacta and Doptelet. A trial of Alvaiz would also count. 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, pulmonologist or immunologist (initial)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	<p>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 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</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	cough, skin rash or abdominal pain, or improvement in function or activities of daily living.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TAZAROTENE

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

# TAZVERIK

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## 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	Epithelioid 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

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## 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

# TEPEZZA

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## 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

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## 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

- BONSITY
- FORTEO
- *teriparatide (preferred ndcs starting with 47781)*

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	<p>INITIAL THERAPY: Postmenopausal Osteoporosis (PMO) Treatment, Increase Bone Mass in Men (see Note 1 below) with Primary or Hypogonadal Osteoporosis, and Treatment of Glucocorticosteroid-Induced Osteoporosis (GIO): (one of A, B, C, D or E): A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (PMO-ibandronate or zoledronic acid, all other diagnoses-zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past. All INDICATIONS: if the request is for brand name Forteo, patient must try teriparatide or Bonsity first. CONTINUATION THERAPY: ALL INDICATIONS: if the patient has taken teriparatide for two years, approve if the patient is at high risk for fracture. Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density. Note 1: a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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

# TEVIMBRA

## Products Affected

- TEVIMBRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. Hepatocellular carcinoma-approve if (A or B): A) medication is used first-line and meets (i or ii): i) pt has liver-confined, unresectable disease and is deemed ineligible for transplant, or ii) pt has extrahepatic/metastatic disease and are deemed ineligible for resection, transplant, or locoregional therapy, or B) medication is being used for subsequent-line therapy. Nasopharyngeal carcinoma-approve if (A and B): A) pt has recurrent, unresectable, oligometastatic, or metastatic disease, and B) meets (i or ii): i) used as first-line treatment in combination with cisplatin and gemcitabine or ii) used as subsequent treatment and (a or b): a) used as a single agent, or b) used in combination with cisplatin and gemcitabine. Small bowel adenocarcinoma-approve if (A, B, C and D): A) locally unresectable or medically inoperable disease, or advanced or metastatic disease, and B) ultra-hypermutated phenotype (defined as tumor mutation burden greater than 50 mutations/megabase), and C) has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation positive disease, and D) is used as a single agent.
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. ESOPHAGEAL and ESOPHAGOGASTRIC JUNCTION CANCERS-All of (A, B and C): A.Meets ONE of the following (i or ii): i.Unresectable locally advanced, recurrent, or metastatic disease, OR ii. Not a surgical candidate, AND B. Meets (i, ii, or iii): i) pt has esophageal squamous cell carcinoma with tumor expression for programmed death-ligand 1 (PD-L1) as determined by an approved test has a combined positive score (CPS) greater than or equal to 1 and medication

PA Criteria	Criteria Details
	<p>is used as first-line or induction therapy and is used in combination with chemotherapy, or ii) pt has esophageal squamous cell carcinoma and Medication is used as a single agent and is used for subsequent therapy, or iii) pt has esophagel adenocarcinoma that is HER2 overexpression negative and tumor expression for PD-L1 as determined by an approved test has a CPS greater than or equal to 1, AND C. Patient has NOT previously received a checkpoint inhibitor or has NO tumor progression while on a checkpoint inhibitor. Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion). Gastric or gastroesophageal junction adenocarcinoma- approve if (A, B, C and D): A) unresectable, recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-negative disease, B) tumor expresses programmed death-ligand 1 (PD-L1) greater than or equal to 1 percent, C) used first line, and D) used in combination with platinum and fluoropyrimidine-based chemotherapy. Anal carcinoma-meets (A and B): A) used as a single agent and B) meets (i or ii): i) locally recurrent, progressive disease and administered before proceeding to abdominoperineal resection, or ii) metastatic disease, used as subsequent therapy and has not received prior immunotherapy [ex: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Libtayo (cemiplimab intravenous infusion), and Jemperli (dostarlimab intravenous infusion)]. CLL/SLL-approve if (A, B and C): A) patient has histologic transformation to diffuse large B-cell lymphoma, and B) has del(17p)/TP53 mutation OR is chemotherapy refractory OR is unable to receive chemoimmunotherapy, and C) is used in combination with Brukinsa (zanubrutinib capsules). Colon, rectal or appendiceal cancer-approve if pt meets (A and B): A) meets (i or ii): i) pt has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease, or ii) has DNA polymerase epsilon/delta (POLE/POLD1) mutation, and B) pt has advanced or metastatic disease.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anal carcinoma, Chronic lymphocytic leukemia/small lymphocytic lymphoma, hepatocellular carcinoma, nasopharyngeal carcinoma, small bowel adenocarcinoma, colon/rectal/appendiceal cancer
<b>Part B Prerequisite</b>	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	<p>Asthma, initial-approve if the patient meets the following criteria (i and ii):</p> <p>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 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</p>

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

# THALOMID

## Products Affected

- THALOMID ORAL CAPSULE 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	MM, myelofibrosis, histiocytic neoplasms-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 has multicentric Castleman's disease and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). Histiocytic neoplasms-approve if pt has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman cutaneous disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi's Sarcoma, Castleman's Disease, histiocytic neoplasms.
<b>Part B Prerequisite</b>	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 oligodendroglioma or 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
Part B Prerequisite	Yes

# TIOPRONIN

## Products Affected

- THIOLA
- THIOLA EC
- *tiopronin*
- *venxxiva*

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

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## 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. Vaginal cancer- approve if the patient has tried at least one chemotherapy agent.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Vaginal cancer
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



# TOFIDENCE IV

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## Products Affected

- TOFIDENCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	ALL DIAGNOSES, INITIAL THERAPY-patient has tried Tyenne IV AND Actemra IV. A trial of the subcutaneous formulation would also count. ALL DIAGNOSES, CONTINUATION THERAPY- patient has responded to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TOLCAPONE

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## 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 or Ongentys (opicapone) 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

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## 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	Aspergillosis - 6 months, Blastomycosis - 12 months, Histoplasmosis - 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
<b>Exclusion Criteria</b>	Concurrent use with Jynarque.
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 30 days for initial therapy, 3 months for continuation of therapy
<b>Other Criteria</b>	Hyponatremia, initial therapy (including new starts, patients on therapy for less than 30 days, and patients restarting therapy) - 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. Hyponatremia, continuation of therapy for patients established on therapy for at least 30 days - approve if the serum sodium level has increased from baseline (prior to initiating the requested drug) OR if the patient experienced improvement in at least one symptom, such as nausea, vomiting, headache, lethargy, or confusion.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TOPICAL AGENTS FOR ATOPIC DERMATITIS

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## 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

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## Products Affected

- *brimonidine topical*
- MIRVASO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Use in the treatment of erythema not caused by rosacea (ie, transient) [eg, during times of stress, sunburn, or skin irritation from cosmetic products].
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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*
- AKLIEF
- ALTRENO
- ATRALIN
- DIFFERIN TOPICAL CREAM
- DIFFERIN TOPICAL GEL WITH PUMP
- DIFFERIN TOPICAL LOTION
- RETIN-A
- RETIN-A MICRO
- *tretinoin microspheres*
- *tretinoin topical*

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for cosmetic use.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# TOPIRAMATE/ZONISAMIDE

## Products Affected

- EPRONTIA
- TOPAMAX
- *topiramate oral capsule, sprinkle 15 mg, 25 mg*
- *topiramate oral capsule, extended release 24hr*
- *topiramate oral capsule, sprinkle, er 24hr*
- *topiramate oral solution*
- *topiramate oral tablet*
- TROKENDI XR
- ZONEGRAN ORAL CAPSULE 100 MG, 25 MG
- ZONISADE
- *zonisamide*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coverage is not provided for weight loss or smoking cessation.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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.
Off-Label Uses	N/A
Part B Prerequisite	No

# TRANSMUCOSAL FENTANYL DRUGS

## Products Affected

- *fentanyl citrate buccal lozenge on a handle 200 mcg*
- FENTANYL CITRATE BUCCAL TABLET, EFFERVESCENT 400 MCG, 600 MCG, 800 MCG

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
- HERCEPTIN HYLECTA
- HERCESSI
- 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, Hercessi 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
Part B Prerequisite	No

# TRELSTAR

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## 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	Prostate cancer: Prescribed by or in consultation with a oncologist or urologist. Head and neck cancer - salivary gland tumors: 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. Prostate cancer: Patients new to therapy, are required to try Eligard or Orgovyx prior to approval of Trelstar. Head and neck cancer - salivary gland tumors: approve if patient has recurrent, unresectable, or metastatic disease and androgen receptor-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Head and neck cancer - salivary gland tumors
Part B Prerequisite	No

# TREMFYA

## Products Affected

- TREMFYA ONE-PRESS
- TREMFYA PEN
- TREMFYA PEN INDUCTION PK(2PEN)
- TREMFYA SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	PP-6 years of age and older (initial therapy), UC/CD- 18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	PP-Prescribed by or in consultation with a dermatologist (initial therapy only). PsA-prescribed by or in consultation with a dermatologist or rheumatologist (initial therapy). UC/CD-prescribed by or in consultation with a gastroenterologist (initial therapy).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	PP, initial therapy - approve if the pt meets (A and B): A) meets (1 or 2): 1) 18 years of age or older, or 2) 6 to 17 years old and weighs at least 40 kg, and B) 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: a biologic that is not a biosimilar of the requested product will also count) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. ULCERATIVE COLITIS-approve. CROHN'S DISEASE (CD): approve. PP/PsA/UC/CD continuation of therapy - approve if the pt is responding to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TREMFYA IV

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## Products Affected

- TREMFYA INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic oral small molecule drug.
Required Medical Information	Diagnosis
Age Restrictions	18 years 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 medication will be used as induction therapy. CROHN'S DISEASE (CD): Approve if the medication will be used as induction therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
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
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
Coverage Duration	Authorization will be for 1 year
Other Criteria	For Wilson's Disease, approve if the patient meets A and B: A) Diagnosis of Wilson's disease is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, or d): a. Presence of Kayser-Fleischer rings, OR b. Serum ceruloplasmin levels less than 20mg/dL, OR c. Liver biopsy findings consistent with Wilson's disease, OR d. 24-hour urinary copper greater than 40 micrograms/24 hours, AND B) Patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant , OR 6) the patient has been started on therapy with trientine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No



# TRIKAFTA

## Products Affected

- TRIKAFTA ORAL GRANULES IN PACKET, SEQUENTIAL
- TRIKAFTA ORAL TABLETS, SEQUENTIAL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko.
<b>Required Medical Information</b>	Diagnosis, specific CFTR gene mutations, concurrent medications
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	CF - Approve if the pt meets A, B and C: A) pt has at least one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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 one systemic regimen, 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.) and has had progression with at least one cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting (Note: Examples of CDK4/6 inhibitor include: Ibrance (palbociclib tablets or capsules), Verzenio (abemaciclib tablets), Kisqali (ribociclib tablets), Kisqali Femara Co-Pack (ribociclib and letrozole tablets) 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
<b>Exclusion Criteria</b>	Rituximab will not be used concurrently with another biologic or with a targeted synthetic DMARD (RA diagnosis)-initial therapy
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA-prescribed by or in consultation with a rheumatologist (initial therapy)
<b>Coverage Duration</b>	RA-1 month, all others-1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TRYNGOLZA

## Products Affected

- TRYNGOLZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by a cardiologist, an endocrinologist, or a physician who focuses in the treatment of disorders related to severe hypertriglyceridemia.
Coverage Duration	1 year
Other Criteria	FAMILIAL CHYLOMICRONEMIA SYNDROME (all of A, B and C): A) Fasting triglyceride level greater than or equal to 880 mg/dL, AND B) Patient has undergone genetic testing and meets ONE of the following (i or ii): i. Molecular genetic test results demonstrate biallelic pathogenic variants in at least one gene causing familial chylomicronemia syndrome. Note: Examples of genes causing Familial Chylomicronemia Syndrome include lipoprotein lipase (LPL), glycosylphosphatidylinositol-anchored high-density lipoprotein-binding protein 1 (GPIHBP1), apolipoprotein A-V (APOA5), apolipoprotein C-II (APOC2), or lipase maturation factor 1 (LMF1), OR ii. Molecular genetic test results are inconclusive and the patient has ONE of the following (a, b, c, d, or e): a) Familial chylomicronemia syndrome score greater than or equal to 10, OR b) North American familial chylomicronemia syndrome score greater than or equal to 45, OR c) History of pancreatitis, OR d) History of eruptive xanthomas, OR e) History of lipemia retinalis, AND C) The medication will be used concomitantly with a low-fat diet.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# TRYVIO

## Products Affected

- TRYVIO

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	<p>HYPERTENSION-approve if the patient has tried, or is currently receiving, at least TWO other antihypertensive agents for the treatment of hypertension from at least TWO of the following pharmacological classes (i, ii, iii, iv, v, vi, vii, viii, ix, x) [A combination product from two or more different classes would count as an alternative from each class]: i. Angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) [e.g., benazepril, lisinopril, candesartan, losartan], ii. Non-dihydropyridine calcium channel blocker (e.g., diltiazem, verapamil), iii. Dihydropyridine calcium channel blocker (e.g., amlodipine, felodipine), iv. Diuretic (e.g., hydrochlorothiazide, chlorthalidone, amiloride), v. Mineralocorticoid receptor antagonist e.g., spironolactone, eplerenone), vi. Beta blocker (e.g., atenolol, metoprolol), vii. Alpha-adrenergic blocker (e.g., doxazosin, terazosin), viii. Central alpha-adrenergic agonist (e.g., clonidine, guanfacine), ix. Direct vasodilator (e.g., hydralazine, minoxidil), x.Direct renin inhibitor (e.g., aliskiren).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# TUKYSA

## Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>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.</p> <p>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)-amplified disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type). Biliary tract cancer- approve if the patient meets all of (a, b, c, and d): a) unresectable or metastatic disease, b) HER2 positive disease, c) tried at least one systemic regimen, d) will use in combination with trastuzumab.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Biliary tract cancer
Part B Prerequisite	No

# TURALIO

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## 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



## TYENNE IV

### Products Affected

- TYENNE INTRAVENOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	<p>INITIAL THERAPY- RHEUMATOID ARTHRITIS (RA) [A OR B]: A) Try TWO of the following: Enbrel, a preferred adalimumab product, Rinvoq, Orencia or Xeljanz. (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the try TWO requirement: Cimzia, infliximab, Simponi (IV/SC), Kevzara or another non-preferred adalimumab product will also count.) OR B) Patient has heart failure or a previously treated lymphoproliferative disorder. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A OR B]: A) Try TWO of the following: Enbrel, Orencia, Rinvoq, Xeljanz, a preferred adalimumab product, (Note: if they have had a trial with infliximab, Kevzara or another non-preferred adalimumab product will also count.) OR B) Patient has heart failure or a previously treated lymphoproliferative disorder. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): Approve. GIANT CELL ARTERITIS: Tried or is currently taking a systemic corticosteroid or corticosteroid is contraindicated. CYTOKINE RELEASE SYNDROME ASSOCIATED WITH CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY-approve. Please Note: preferred adalimumab products Humira (NDCs starting with -00074), Cyltezo, Yuflyma. CONTINUATION THERAPY-RA, PJIA, SJIA, GCA:patient has responded to therapy.</p>

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

# TYMLOS

## Products Affected

- TYMLOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Previous medications tried, renal function
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 2 years of total therapy over a patient's lifetime
<b>Other Criteria</b>	Postmenopausal Osteoporosis (PMO) Treatment and Osteoporosis Treatment in Men (see Note 1 below) [one of A, B, C, D, or E]: A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (PMO-ibandronate or zoledronic acid, osteoporosis in men- zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past. ALL INDICATIONS: must have a trial of teriparatide prior to approval of Tymlos. Note 1: a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TYSABRI

## Products Affected

- TYSABRI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Adults (initial and continuation)
<b>Prescriber Restrictions</b>	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).
<b>Coverage Duration</b>	MS-Authorization will be for 1 year .CD, initial-6 mo. CD, cont therapy-1 year.
<b>Other Criteria</b>	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 moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein) and patient has tried two advanced therapies indicated for the use in CD (for example: adalimumab, certolizumab pegol, infliximab, vedolizumab, ustekinumab, risankizumab, and upadacitinib),

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

# TYVASO DPI

## Products Affected

- TYVASO DPI INHALATION 16(112)-32(112) -48(28) MCG, 32 MCG, CARTRIDGE WITH INHALER 16 MCG, 48 MCG, 64 MCG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with oral or parenteral prostacyclin agents used for pulmonary hypertension
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Pulmonary Hypertension w/Interstitial lung disease - 18 years and older (initial/cont)
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a cardiologist or a pulmonologist (initial and continuation).
<b>Coverage Duration</b>	PAH, WHO Group 1-1 year (initial/cont). Pulmonary HTN w/lung disease-Initial-4 months, cont-1 year
<b>Other Criteria</b>	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. Note: 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 (A, B and C): A) the patient has had a right heart catheterization to confirm the diagnosis and B) if the patient has connective tissue disease, the pt must have a baseline forced vital capacity less than 70 percent and C) the patient has evidence of diffuse parenchymal lung disease 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.

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

# UBRELVY

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## 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-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 a physician who has 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 meets one of the following: 1) 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), 2) 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 3) 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 Fulphila and Nyvepria and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse

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

# ULTOMIRIS

## Products Affected

- ULTOMIRIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with another complement inhibitor, a rituximab product, a Neonatal Fc Receptor Blocker, Enspryng or Uplizna
<b>Required Medical Information</b>	Diagnosis, test results
<b>Age Restrictions</b>	MG/NMOSD-18 years and older (initial/cont)
<b>Prescriber Restrictions</b>	PNH-Prescribed by or in consultation with a hematologist (initial/cont). aHUS-prescribed by or in consultation with a nephrologist. MG/NMOSD-prescribed by or in consultation with a neurologist (initial/cont).
<b>Coverage Duration</b>	PNH/MG-Initial 6 months, cont-1 year, aHUS-1 year, NMOSD-1 year
<b>Other Criteria</b>	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. 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. 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, 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.

<b>PA Criteria</b>	<b>Criteria Details</b>
	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. NMOSD, initial-approve if the diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody. NMOSD, continuation-approve if the diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody and if the patient has had clinical benefit from use of Ultomiris (e.g., reduction in relapse rate, reduction in symptoms, slowing progression in symptoms).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# UPLIZNA

## Products Affected

- UPLIZNA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with a rituximab product, Enspryng, Ultomiris or Soliris
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial and continuation)
<b>Prescriber Restrictions</b>	NMOSD-prescribed by or in consultation with a neurologist (initial and continuation). IgG4-RD-prescribed by or in consultation with an endocrinologist, gastroenterologist, immunologist, nephrologist, neurologist, pulmonologist, rheumatologist, or a physician who specializes in treating immune-mediated disorders (initial and continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Immunoglobulin G4-related disorders (IgG4-RD), initial- approve if pt meets (A and B): A) pt has had a history of involvement of at least one organ, and B) meets one of (i or ii): i) received or is currently receiving a systemic corticosteroid, or ii) had inadequate efficacy, a contraindication, or significant intolerance to a systemic corticosteroid. IgG4-RD, continuation- approve if patient has had clinical benefit from the use of Uplizna. Neuromyelitis Optica Spectrum Disorder initial-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive. NMOSD, 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# UPTRAVI

## Products Affected

- UPTRAVI INTRAVENOUS
- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLETS,DOSE PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.
<b>Required Medical Information</b>	Confirmation of right heart catheterization, medication history (as described in Other Criteria)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VABYSMO

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## 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

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## 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

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## 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

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## 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, re-induction, consolidation, or maintenance treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# VANRAFIA

## Products Affected

- VANRAFIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other medications indicated for the treatment of immunoglobulin A nephropathy
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial and continuation)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist (initial and continuation)
<b>Coverage Duration</b>	9 months
<b>Other Criteria</b>	<p>PRIMARY IMMUNOGLOBULIN A NEPHROPATHY, INITIAL-All of the following (i and ii): i. Diagnosis has been confirmed by biopsy, AND ii. Patient is at high risk of disease progression, defined by meeting BOTH of the following (a and b): a. Patient meets ONE of the following [(1) or (2)]: 1. Proteinuria greater than or equal to 0.5 g/day, OR 2. Urine protein-to-creatinine ratio greater than or equal to 1.5 g/g, AND b. Patient has received or is currently receiving the maximum or maximally tolerated dose of ONE of the following prior to starting Vanrafia [(1) or (2)]: 1. Angiotensin converting enzyme inhibitor, OR 2. Angiotensin receptor blocker. PRIMARY IMMUNOGLOBULIN A NEPHROPATHY, CONTINUATION- All of the following (i and ii): i. Diagnosis has been confirmed by biopsy, AND ii. Patient has had a response to Vanrafia, Note: Examples of a response are a reduction in urine protein-to-creatinine ratio from baseline, reduction in proteinuria from baseline.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VELSIPITY

## Products Affected

- VELSIPITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs) for ulcerative colitis.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist (initial therapy only)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	Ulcerative colitis, initial therapy-approve if the patient has had a trial of TWO of the following: a preferred adalimumab product, a preferred ustekinumab product, Skyrizi, Tremfya, a preferred infliximab product, Rinvoq. A trial of a non-preferred infliximab product, a non-preferred ustekinumab, 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. Please Note: preferred adalimumab products include Humira (NDCs starting with - 00074), Cyltezo, Yuflyma. Preferred infliximab products include Remicade, Zymfentra. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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 (all diagnoses except ALL)
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML-approve if used in combination with azacitidine, decitabine, or cytarabine. CLL/SLL- approve. ALL- approve if relapsed/refractory disease and will be used in combination with chemotherapy. Hairy cell leukemia- approve if disease resistance to BRAF inhibitor therapy. Mantle Cell Lymphoma- approve if (A or B): A) the patient has tried at least one systemic regimen or B) patient has TP53 mutation and will use this as induction therapy in combination with Brukinsa (zanubrutinib) and Gazyva (obinutuzumab intravenous infusion). MDS- approve if pt meets (A and B): A) pt meets (i or ii): (i) has chronic myelomonocytic leukemia-2 or (ii) has higher risk disease (note: includes international prognostic scoring system (IPSS-R) intermediate-, high-, or very-high risk disease) and B) will use in combination with azacitidine or decitabine. Myeloproliferative neoplasm- approve if pt has accelerated or blast phase disease and will use in combination with azacitidine or decitabine. 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 Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Mantle Cell Lymphoma, waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, multiple myeloma, systemic light chain amyloidosis, acute lymphoblastic leukemia, hairy cell leukemia, myelodysplastic syndrome, myeloproliferative neoplasm
<b>Part B Prerequisite</b>	No

# VEOPOZ

## Products Affected

- VEOPOZ

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other complement inhibitors
Required Medical Information	Diagnosis
Age Restrictions	1 year and older (initial/continuation)
Prescriber Restrictions	Prescribed by a physician with expertise in managing CHAPLE disease (initial/continuation)
Coverage Duration	Initial-3 months, continuation-1 year
Other Criteria	<p>CD55-Deficient Protein-Losing Enteropathy (CHAPLE Disease [Complement Hyperactivation, Angiopathic thrombosis, and Protein-Losing Enteropathy])-Approve if the patient meets A or B: A) Initial Therapy-Approve if the patient meets the following (i, ii and iii): i.Patient has had a genetic test confirming the diagnosis of CHAPLE disease with a biallelic CD55 loss-of-function mutation [documentation required], AND ii.Patient meets both of the following (a and b): a)Patient has a serum albumin level less than or equal to 3.2 g/dL [documentation required], AND b)the patient has active disease and is experiencing one or more signs or symptoms within the last 6 months, Note: Examples of signs and symptoms include abdominal pain, diarrhea, vomiting, peripheral edema, or facial edema. AND, iii. Patient meets all of the following (a and b): a) Patient has received or is in compliance with updated meningococcal vaccinations according to the most current Advisory Committee on Immunization Practices recommendations, AND b) Patient has received or is in compliance with updated vaccinations for the prevention of Streptococcus pneumonia and Haemophilus influenza type b infections according to the most current Advisory Committee on Immunization Practices guidelines. B)Patient Currently Receiving Veopoz-Approve if the patient meets the following (i and ii): i.Patient has had a genetic test confirming the diagnosis of CHAPLE disease with a biallelic CD55 loss-of-function mutation [documentation required], AND ii.Patient had</p>



PA Criteria	Criteria Details
	<p>experienced a response to therapy [documentation required]. Note: Examples of a response to therapy include increased serum albumin levels, maintenance of serum albumin levels within a normal range, a reduction in albumin transfusions, increases in or maintenance of protein and/or immunoglobulin levels, improvement in clinical outcomes after receipt of therapy (e.g., decreases in the frequency of problematic abdominal pain, bowel movement frequency, facial edema severity, and peripheral edema severity), reduced frequency in hospitalizations, increase in growth percentiles (e.g., body weight-for age and/or stature-for-age percentiles), and/or reduced use of corticosteroids.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VEOZAH

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## 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	<p>Vernal keratoconjunctivitis-approve if the patient has moderate to severe vernal keratoconjunctivitis and patient meets one of the following (i or ii):</p> <p>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, Lastacraft, 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 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%</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	ophthalmic solution], Restasis [cyclosporine 0.05% ophthalmic emulsion]) other than the requested medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VERZENIO

## Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: 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	<p>Breast Cancer, Early-pt meets (A,B,C and D): A)Pt HR+disease, AND B) HER2-negative breast cancer, AND C)node-positive disease at high risk of recurrence AND D)meets 1 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 postmenopausal woman, OR b)Pt is pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets 1 of the following (a or b): a)Pt is postmenopausal woman or man OR b)Pt is pre/perimenopausal woman and meets 1 of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Recurrent or Metastatic in Women-pt meets (A, B and C): A)has HR+ disease, AND B)Pt meets 1 of following criteria (i or ii): i.Pt is postmenopausal woman, OR ii.Pt is pre/perimenopausal woman and meets 1 of the following (a or b): a)receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt had surgical bilateral oophorectomy or ovarian irradiation, AND C) either (1 or 2): 1) HER2-negative breast cancer and Pt meets 1 of 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</p>

PA Criteria	Criteria Details
	<p>fulvestrant, OR iii.pt meets following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)has tried chemo for metastatic breast cancer or 2)has HER2-positive breast cancer and has received at least 3 prior anti-HER2-based regimens in metastatic setting and will use this in combo with fulvestrant and trastuzumab.Breast Cancer-Recurrent or Metastatic in Men-pt meets following criteria (A and B): A)HR+ disease, AND B)either (1 or 2): 1) HER2-negative disease and Pt meets 1 of following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)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 1 prior endocrine therapy, AND c)Pt has tried chemo for metastatic breast cancer, or 2) has HER2-positive disease and has received at least 3 prior anti-HER2-based regimen in metastatic setting and will use this medication in combo with fulvestrant and trastuzumab. Endometrial cancer-pt meets all of (A, B, And C): A)has recurrent or metastatic disease, and B)has estrogen receptor (ER)-positive tumors, and C)will be using in combination with letrozole.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Endometrial cancer
<b>Part B Prerequisite</b>	No

# VIGABATRIN

## Products Affected

- SABRIL
- *vigabatrin*
- *vigadrone*
- VIGAFYDE
- *vigpoder*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medication history (complex partial seizures)
<b>Age Restrictions</b>	Refractory complex partial seizures - patients 2 years of age or older. Infantile spasms - patients less than or equal to 2 years of age
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist
<b>Coverage Duration</b>	Infantile spasms- 6 mo. Treatment-Refractory Partial Seizures-initial therapy 3 mo, cont-1 year
<b>Other Criteria</b>	Infantile spasms-requested medication is being used as monotherapy. Treatment refractory complex partial seizures initial-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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VIJOICE

## Products Affected

- VIJOICE ORAL GRANULES IN PACKET
- 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 Vioice for at least 6 months and has experienced a reduction in volume from baseline (prior to initiating Vioice) 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 Vioice) Note: Examples of signs or symptoms of PROS include pain, fatigue, vascular malformation, limb asymmetry, or disseminated intravascular coagulation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No



# VILTEPSO

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## 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

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## 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 biallelic pathogenic or likely pathogenic N-acetylgalactosamine-6-sulfatase gene variants.
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	Pediatric Diffuse High-Grade Glioma- less than or equal to 21 years old
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. Pediatric diffuse high grade glioma - approve if (A and B): A) tumor is positive for NTRK gene fusion and B) meets (i or ii): i) medication is used as adjuvant therapy or ii) medication is used 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

# VIVJOA

## Products Affected

- VIVJOA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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))
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	4 months
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VIZIMPRO

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## 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, B, or C): (A) the patient has a platelet count of less than $50 \times 10^9$ /L (less than 50,000/mcL) OR (B) Patient has a platelet count of greater than or equal to $50 \times 10^9$ /L (greater than or equal to 50,000/mcL) and has high-risk disease, OR (C) patient has myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease- related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Accelerated or blast phase myeloproliferative neoplasm
Part B Prerequisite	No

# VORANIGO

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## Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

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	GLIOMAS-All of (A, B and C): A. Susceptible isocitrate dehydrogenase-1 (IDH1) or IDH2 mutation-positive disease, AND B. Grade 2 oligodendroglioma OR Grade 2 astrocytoma, AND C. Prior surgery, including biopsy, sub-total resection, or gross total resection
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# VORICONAZOLE (ORAL)

## Products Affected

- VFEND ORAL SUSPENSION FOR RECONSTITUTION
- 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

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## Products Affected

- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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 oral tablet 200 mg
- 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	<p>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.</p> <p>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.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (ie, papillary, follicular, oncocytic carcinoma) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or

<b>PA Criteria</b>	<b>Criteria Details</b>
	Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma, bone cancer.
<b>Part B Prerequisite</b>	No

# VOWST

## Products Affected

- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	30 days
Other Criteria	Prevention of recurrence of clostridioides difficile infection (CDI)-approve if the patient has completed a bowel prep (or will start a bowel prep the day before and at least 8 hours prior to taking the first dose), will not eat or drink for at least 8 hours prior to the first dose and will complete their antibacterial treatment for recurrent CDI 2-4 days before initiating treatment with Vowst and Vowst will not be used for the TREATMENT of CDI.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# VOXZOGO

## Products Affected

- VOXZOGO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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]
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Less than 18 years old (initial and continuation)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist (initial and continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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 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).</p>
<b>Indications</b>	All FDA-approved Indications.

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

# VOYDEYA

## Products Affected

- VOYDEYA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with Empaveli (pegcetacoplan subcutaneous injection) or Fabhalta (iptacopan capsules).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial/continuation)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist (initial/continuation)
<b>Coverage Duration</b>	Initial-3 months, Continuation-1 year
<b>Other Criteria</b>	<p>INITIAL THERAPY-PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)-All of (i, ii, iii): i) peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins on at least two cell lineages and ii) prescribed in combination with Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab-cwvz intravenous infusion) and iii) clinically significant extravascular hemolysis (while receiving Soliris or Ultomiris) as evidenced by objective laboratory findings (see Note 1).</p> <p>CONTINUATION THERAPY-PNH-medication is prescribed in combination with Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab intravenous infusion) AND patient is continuing to derive benefit from Voydeya (see Note 2). Note 1: Examples of objective laboratory findings include reduction in hemoglobin levels, elevated reticulocyte counts, increased transfusion requirements, transfusion-dependence. Note 2: Examples of benefit include increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis, improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No



# VPRIV

## Products Affected

- VPRIV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other approved therapies for Gaucher disease such as Cerdelga (eliglustat capsules), Elelyso (taliglucerase alfa injection), Cerezyme (imiglucerase injection), and Zavesca (miglustat capsules).
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results
<b>Age Restrictions</b>	Greater than or equal to 4 years of age
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Gaucher Disease, Type 1 (non-neuronopathic Gaucher disease)-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene. Gaucher Disease, Type 3 (chronic neuronopathic Gaucher disease)-approve if both (A and B): A) there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene, and B) medication is not being used for management of neurological manifestations AND is being used for management of impaired growth, hematologic, or visceral symptoms.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Type 3 Gaucher Disease
<b>Part B Prerequisite</b>	No

# VTAMA

## Products Affected

- VTAMA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	PP-18 years and older, AD-2 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	1 year
Other Criteria	<p>Plaque Psoriasis: Approve if patient has psoriasis involvement estimated to affect less than or equal to 20 percent of the body surface area and meets (A or B): A) Patient is treating plaque psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia OR B) Meets (i and ii): i) Patient has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid, AND Inadequate efficacy was demonstrated with this topical corticosteroid and ii) Patient has tried at least one topical vitamin D analog, (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 0.064% suspension (Taclonex, generic. Concomitant use of a topical vitamin d analog and a topical corticosteroid would meet the requirement) AND Inadequate efficacy was demonstrated with this topical vitamin D analog. Atopic Dermatitis-Try TWO of the following: pimecrolimus cream (Elidel cream, generics), tacrolimus ointment, Eucrisa, or topical corticosteroid.</p>
Indications	All FDA-approved Indications.

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

# VUITY

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## Products Affected

- *pireloarpine hcl ophthalmic (eye) drops*  
1.25 %
- 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

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## Products Affected

- VUMERITY

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

# VYALEV

## Products Affected

- VYALEV

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	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. PARKINSON'S DISEASE - All of (A, B, C and D): A. Diagnosed with advanced Parkinson's disease, AND B. Experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, AND C. Tried an oral carbidopa/levodopa therapy and experienced significant intolerance or inadequate efficacy, AND D. Tried or currently receiving ONE other treatment for off episodes. Note: Examples of treatment for off episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Ogmentys (opicapone capsules), or Xadago (safinamide tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# VYEPTI

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## Products Affected

- VYEPTI

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with another cGRP for migraine headache prevention
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 meets all of (A, B and C): A) pt has greater than or equal to 4 migraine days per month (prior to initiating migraine-preventive medication), and B) pt has tried Aimovig and Emgality and C) if the patient is currently taking Vyepti, pt has had significant clinical benefit from the medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# VYJUVEK

## Products Affected

- VYJUVEK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with Filsuvez (birch triterpenes topical gel).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	6 months and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist or wound care specialist (initial and continuation)
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Dystrophic epidermolysis bullosa, initial therapy-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 AND the target wound(s) meet the following (1, 2, and 3): 1) clean in appearance and does not appear to be infected, and 2) has adequate granulation tissue and vascularization, and 3) Squamous cell carcinoma has been ruled out for the target wound(s). Note: Examples of clinical features of dystrophic epidermolysis bullosa include but are not limited to blistering, wounds, and scarring. Dystrophic epidermolysis bullosa, continuation therapy [new wounds or reopened recurrent wounds- use initial therapy criteria]-approve if target wound(s) remain open AND decreased in size from baseline.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# VYKAT XR

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## Products Affected

- VYKAT XR

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 endocrinologist or geneticist
Coverage Duration	1 year
Other Criteria	PRADER-WILLI SYNDROME-diagnosis has been established by identification of abnormal DNA methylation of chromosome 15q11.2Q13, AND patient has hyperphagia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# VYLOY

## Products Affected

- VYLOY

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. GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA (all of A, B, C, D and E): A. Unresectable locally advanced, recurrent or metastatic disease, AND B. Tumor is claudin 18.2 positive as determined by an approved test, Note: Claudin 18.2 positivity is defined as greater than or equal to 75 percent of tumor cells demonstrating moderate to strong membranous claudin 18.2 immunohistochemical staining. AND C. Tumor is human epidermal growth factor receptor 2 (HER2)-negative, AND D. Used for first-line treatment, AND E. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy. Note: Examples of fluoropyrimidines include 5-fluorouracil and capecitabine. Examples of platinum chemotherapy agents include oxaliplatin. Esophageal adenocarcinoma- all of (A, B, C, D and E): A. unresectable locally advanced, recurrent, or metastatic disease, AND B. tumor is is claudin 18.2 positive as determined by an approved test, AND C. tumor is human epidermal growth factor receptor 2 (HER2)-negative, and D. used for first-line treatment, AND E. used in combination with fluoropyrimidine- and platinum-containing chemotherapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Esophageal adenocarcinoma

PA Criteria	Criteria Details
Part B Prerequisite	No

# VYONDYS

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## 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
<b>Exclusion Criteria</b>	Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, or a Rituximab Product
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (CIDP: initial only, GMG: initial and continuation)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist (CIDP: initial only, GMG: initial and continuation)
<b>Coverage Duration</b>	Initial-6 months, Continuation-1 year
<b>Other Criteria</b>	<p>CIDP (Vyvgart Hytrulo only), Initial Therapy - approve if diagnosis was supported by electrodiagnostic studies AND pt previously received treatment with an intravenous or subcutaneous immune globulin and had inadequate efficacy or significant intolerance or patient has a contraindication to IV or SC immune globulin.. Generalized myasthenia gravis, Initial Therapy-Approve if the patient meets the following criteria (A, B, and C): A. Patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis, AND B. 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 C. patient has myasthenia gravis foundation of america classification of II to IV. CIDP (Vyvgart Hytrulo only), Cont therapy - pt has clinically significant improvement in neurologic symptoms (Examples include improvement in disability: nerve conduction study results improved or stabilized, physical examination shows improvement in neurological symptoms, strength, and sensation). Generalized myasthenia gravis, Continuation Therapy-Approve if patient is continuing to derive benefit from Vyvgart. For gMG: All treatment cycles should be no more frequent than every 50 days from the start of the previous treatment cycle.</p>
<b>Indications</b>	All FDA-approved Indications.

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

# WAINUA

## Products Affected

- WAINUA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with Amvuttra (vutrisiran subcutaneous injection), Onpattro (patisiran intravenous infusion), Tegsedi (inotersen subcutaneous injection), or a Tafamidis Product.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR)-Approve if the patient meets ALL of the following (A, B and C):</p> <p>A) Patient has a transthyretin mutation as confirmed by genetic testing, AND B) Patient has symptomatic polyneuropathy, 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. AND C) Patient does not have a history of liver transplantation.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# WAKIX

## Products Affected

- WAKIX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of Wakix with an oxybate product and/or Sunosi (solriamfetol tablets).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	EDS with narcolepsy - 6 years and older. Cataplexy with narcolepsy - 18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consult with a sleep specialist physician or a neurologist
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Excessive daytime sleepiness associated with Narcolepsy-Approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT) AND if pt is 18 years and older, pt must meet (1 or 2): 1) 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 2) 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# WEGOVY

## Products Affected

- WEGOVY SUBCUTANEOUS PEN                      ML, 1 MG/0.5 ML, 1.7 MG/0.75 ML, 2.4  
INJECTOR 0.25 MG/0.5 ML, 0.5 MG/0.5                      MG/0.75 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other glucagon-like peptide-1 (GLP-1) agonists or GLP-1/ glucose-dependent insulintropic polypeptide (GIP) receptor agonists
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	MASH, initial and cont: prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	To reduce the risk of major adverse cardiovascular events in a patient with established cardiovascular disease who is either obese or overweight: approve if the patient meets (A, B, C and D): A) at baseline, the patient has body mass index greater than or equal to 27 kg/m <sup>2</sup> (refers to baseline prior to Wegovy) AND B) the patient meets one of the following (a, b, or c): a) prior myocardial infarction, b) prior stroke or c) history of symptomatic peripheral arterial disease as evidenced by one of the following: (1) intermittent claudication with ankle-brachial index less than 0.85, (2) peripheral arterial revascularization procedure, or (3) amputation due to atherosclerotic disease AND C) the medication will be used in combination with pharmacotherapy for established cardiovascular disease as deemed appropriate by the prescribing physician AND D) the medication will be used in combination with a reduced calorie diet (e.g. Prescriber attestation that patient has received counseling on diet). Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH), initial: approve if patient meets (A, B, C and D): A) does not have cirrhosis, B) meets (i or ii): i) Liver biopsy performed within 3 years preceding treatment with Wegovy showing non-alcoholic fatty liver disease activity score of greater than or equal to 4 with a score of greater than or equal to 1 in ALL of the following: steatosis, ballooning and lobular

PA Criteria	Criteria Details
	inflammation, or ii) One of the following within 6 months preceding treatment with Wegovy (1, 2 or 3): 1) Elastography (e.g. vibration-controlled transient elastography (e.g., FibroScan), transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography) or 2) Computed tomography or 3) Magnetic resonance imaging, and C) stage F2 or F3 fibrosis prior to Wegovy and D) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise). MASH/NASH, continuation: All of (A, B and C): A) completed greater than or equal to 1 year of therapy and has not had worsening of fibrosis or MASH/NASH, and B) has not progressed to stage F4 (cirrhosis) and C) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise).
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	Pheochromocytoma/paraganglioma-12 years and older, Other indications-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Pheochromocytoma/paraganglioma- approve if pt has locally advanced, unresectable, or metastatic disease. 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.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# WINLEVI

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## 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

# WINREVAIR

## Products Affected

- WINREVAIR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	INITIAL THERAPY-PULMONARY ARTERIAL HYPERTENSION (PAH) WHO GROUP 1-All of (A, B, C): A) right-heart catheterization to confirm the diagnosis, and B) Functional Class II or III or IV, and C) One of (a or b): a)currently receiving at least two other PAH therapies from the following different pharmacologic categories, each for greater than or equal to 60 days: phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), and prostacyclins or b) currently receiving at least one other PAH therapy for greater than or equal to 60 days and is intolerant to combination therapy with a phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), or prostacyclin. CONTINUATION THERAPY-PAH WHO GROUP 1-patient has had a right heart catheterization to confirm the diagnosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# XALKORI

## Products Affected

- XALKORI ORAL CAPSULE
- XALKORI ORAL PELLETT 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 or Lorbrena 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 relapsed or refractory disease. 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 inoperable. Melanoma, cutaneous-approve if the patient has ALK fusion disease or ROS1 fusion disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous.
<b>Part B Prerequisite</b>	No



# XDEMVY

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## 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
<b>Exclusion Criteria</b>	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].
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	AS/PsA/RA/UC-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	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. (all apply to initial therapy only)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	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. UC-Approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis or was unable to tolerate a 3-month trial. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis]-initial-approve Xeljanz immediate release tablets or solution if the patient meets the following: patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AS-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least 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.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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 sphingomyelinase (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

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## Products Affected

- XEOMIN

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for cosmetic uses
Required Medical Information	N/A
Age Restrictions	Chronic sialorrhea/Upper limb spasticity-2 years and older. Blepharospasm/Cervical Dystonia-18 years and older.
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
Part B Prerequisite	No

# XIFAXAN

## Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Traveler's diarrhea - 12 years of age or older. Hepatic encephalopathy, irritable bowel syndrome with diarrhea - 18 years of age or older.
Prescriber Restrictions	Pouchitis - prescribed by or in consultation with a gastroenterologist
Coverage Duration	Enceph-6 mo, IBS w/diarrhea-14 days, TD-3 days, intest bact overgrowth-14 days, Pouchitis - 1 year
Other Criteria	Hepatic Encephalopathy-approve Xifaxan 550 mg tablets if the patient has previously had overt hepatic encephalopathy and the requested medication will be used concomitantly with lactulose, unless the patient has a contraindication or significant intolerance to treatment with lactulose. Irritable bowel syndrome with diarrhea-approve Xifaxan 550 mg tablets. Travelers Diarrhea-approve Xifaxan 200 mg tablets if the patient is afebrile and does not have blood in the stool. Small intestine bacterial overgrowth-approve Xifaxan 200mg or 550 mg tablets if the diagnosis has been confirmed by a glucose hydrogen breath test, lactulose hydrogen breath test, or small bowel aspiration and culture. Chronic antibiotic-dependent pouchitis- approve Xifaxan 200mg or 550mg tablets if patient meets all of (a, b, c and d): a) recurrent pouchitis (Note: recurrent pouchitis is typically considered history of at least 3 pouchitis episodes within a 12 month period), and b) episodes of pouchitis respond to antibiotic therapy but relapse shortly after antibiotic discontinuation, and c) alternative causes of recurrent pouchitis have been ruled out, and d) has tried long-term antibiotic therapy trials (at least 4 weeks) of BOTH ciprofloxacin and metronidazole for remission maintenance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Small intestine bacterial overgrowth, chronic antibiotic-dependent pouchitis
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	Concurrent use with another monoclonal antibody therapy.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years and older. Food Allergy-1 yr and older
<b>Prescriber Restrictions</b>	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. Food allergy- allergist or immunologist
<b>Coverage Duration</b>	asthma/CIU-Initial tx 4 months, Polyps-initial-6 months, continued tx 12 months, Food allergy-1 yr
<b>Other Criteria</b>	MODERATE TO SEVERE PERSISTENT ASTHMA (A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, and B) baseline positive skin test or in vitro test for 1 or more perennial or seasonal aeroallergens C) received at least 3 months of combination therapy with an inhaled corticosteroid (ICS) and additional asthma controller/maintenance medication (e.g., LABA, LAMA, leukotriene receptor antagonist, monoclonal antibody) [see Exception 1 below] and D) asthma is uncontrolled or was uncontrolled prior to receiving Xolair or another monoclonal antibody and meets one of the following (a, b, c, d, or e): a) experienced two or more asthma exacerbations requiring systemic CSs in the past year, b) experienced one or more asthma exacerbation requiring hospitalization/urgent care visit/emergency department visit in the past year, c) forced expiratory volume in 1 second (FEV1) less than 80% predicted, d) FEV1/forced vital capacity (FVC) less than 0.80, or e) asthma worsens upon tapering of oral CS. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRwNP) [all of A, B, C, D, and E]: A) diagnosis by

PA Criteria	Criteria Details
	<p>direct exam, endoscopy, or sinus CT scan, B) baseline (prior to Xolair or another monoclonal antibody that may lower IgE) IgE at least 30 IU/ml, C) at least two of the following symptoms for 6 months: nasal congestion, obstruction, discharge, reduction/loss of smell, D) tried intranasal CS and will continue in combination with Xolair, and E) one of the following (a, b, or c): a) had systemic CS at least 5 days in past 2 years, b) contraindication to systemic CS, or c) had nasal polyp surgery. CHRONIC IDIOPATHIC URTICARIA (CIU): urticaria more than 6 weeks prior to treatment with Xolair with symptoms present more than 3 days per week despite daily non-sedating H1-antihistamine therapy. IgE-MEDIATED FOOD ALLERGY (all of A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, B) positive skin prick test or positive in vitro test for IgE to one or more foods, C) history of allergic reaction that met all of the following (a, b, and c): a) signs and symptoms of a significant systemic allergic reaction, b) reaction occurred within a short period of time following a known ingestion of the food, and c) prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector, and D) patient has been prescribed an epinephrine auto-injector.</p> <p>CONTINUATION THERAPY: ASTHMA: patient responded to therapy and continues to receive an ICS. CRwNP: patient responded after 6 months of therapy and continues intranasal CS. CIU: patient responded to therapy. Exception 1: an exception to the requirement of 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.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XOLREMDI

## Products Affected

- XOLREMDI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, hematologist or dermatologist (initial)
Coverage Duration	1 year
Other Criteria	<p>INITIAL THERAPY-WARTS, HYPOGAMMAGLOBULINEMIA, INFECTIONS AND MYELOKATHEXIS (WHIM) SYNDROME-genetic testing confirms pathogenic and or likely pathogenic variants in the CXCR4 gene and at baseline the patient has an absolute neutrophil count less than or equal to 400 cells/microliter, or at baseline, patient had a white blood cell count less than or equal to 400 cells/microliter.</p> <p>CONTINUATION-WHIM SYNDROME-patient is continuing to derive benefit from Xolremdi as determined by the most recent (i.e., within the past 6 months) objective measurement. Note: Examples of objective measurements of a response to Xolremdi therapy are reduced frequency, duration, or severity of infections, less frequent treatment with antibiotics, fewer warts, or improved or stabilized clinical signs/symptoms of WHIM syndrome (e.g., absolute neutrophil count, white blood cell count, and absolute lymphocyte count).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# XOSPATA

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## 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 disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Lymphoid, Myeloid Neoplasms
Part B Prerequisite	No

# XPOVIO

## Products Affected

- XPOVIO

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	<p>Multiple Myeloma-Approve if the patient meets the following (A and B):</p> <p>A) The medication will be taken in combination with dexamethasone AND</p> <p>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 (daratumumab infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples of regimens for multiple myeloma include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Kyprolis (carfilzomib infusion)/Revlimid/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma 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.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Treatment of multiple myeloma in combination with daratumumb or pomalidomide
<b>Part B Prerequisite</b>	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) analog [for example: 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 subcutaneous injection), Orgovyx (relugolix tablets)] 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



# XYREM

## Products Affected

- SODIUM OXYBATE (PREFERRED NDCS STARTING WITH 00054)
- 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, dextroamphetamine) 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 or ii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog [examples: 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 subcutaneous injection), Orgovyx (relugolix tablets)] OR ii. The patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# YORVIPATH

## Products Affected

- YORVIPATH SUBCUTANEOUS PEN  
INJECTOR 168 MCG/0.56 ML, 294  
MCG/0.98 ML, 420 MCG/1.4 ML

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 or nephrologist (initial therapy)
Coverage Duration	1 year
Other Criteria	INITIAL, CHRONIC HYPOPARATHYROIDISM-all of (A and B): A. 25-hydroxyvitamin D stores within normal range (at baseline before initiating Yorvipath therapy), and B. Meets ONE of the following (i or ii): i. Albumin-corrected serum calcium concentration greater than or equal to 7.8 mg/dL at baseline before initiating Yorvipath therapy, or ii. Ionized serum calcium greater than or equal to 4.4 mg/dL at baseline before initiating Yorvipath therapy . CONTINUATION, CHRONIC HYPOPARATHYROIDISM- responding to Yorvipath therapy, according to the prescriber.
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	Diagnosis
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/Radiation- 1 mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)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), 2)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), 3)patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgramstim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy, has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm3], neutropenia expected

PA Criteria	Criteria Details
	<p>to be greater than 10 days in duration, invasive fungal infection). For all diagnoses except PBPC, patients are required to try Releuko and Nivestym and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Zarxio unless patient has initiated therapy with Zarxio and requires additional medication to complete the current cycle of chemotherapy. For PBPC, patients are required to try Nivestym and cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Zarxio, unless patient has initiated therapy with Zarxio and requires additional medication to complete the current cycle of chemotherapy.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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)
<b>Part B Prerequisite</b>	No

# ZAVZPRET

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## 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 TABLET

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 new to therapy they must have a trial of Lynparza prior to approval of Zejula. Patients who have had a complete or partial response to first-line platinum based chemotherapy and do not have BRCA altered disease are not required to try Lynparza. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen. In addition, patients new to therapy must have a trial of Lynparza prior to approval of Zejula. Ovarian, fallopian tube or primary peritoneal cancer in the treatment setting-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma, Ovarian, fallopian tube or primary peritoneal cancer-treatment
Part B Prerequisite	No



# ZELAPAR

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## 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	<p>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, c or d): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma/neuroglioma/glioneuronal tumor OR d) pediatric diffuse high-grade glioma OR ii. Recurrent or progressive disease for one of the following conditions (a or b): a) glioma/circumscribed glioma OR b) Glioblastoma OR iii. Melanoma with brain metastases AND the medication will 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. Multisystem disease OR ii. Pulmonary disease OR iii. Central nervous system lesions AND the patient has BRAF V600-mutation positive disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
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 oncocytic carcinoma) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm
Part B Prerequisite	No

# ZEPATIER

## Products Affected

- ZEPATIER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin or Sovaldi.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation w/ GI, hepatologist, ID, or liver transplant MD.
<b>Coverage Duration</b>	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1 or 4 must try TWO of the following: ledipasvir/sofosbuvir, velpatasvir/sofosbuvir, Mavyret, Vosevi, unless ledipasvir/sofosbuvir, velpatasvir/sofosbuvir, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance
<b>Part B Prerequisite</b>	No

# ZEPBOUND

## Products Affected

- ZEPBOUND

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other glucagon-like peptide-1 (GLP-1) agonists or GLP-1/ glucose-dependent insulintropic polypeptide (GIP) receptor agonists
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial/continuation)
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Obstructive sleep apnea (OSA), moderate to severe, in a patient with obesity, initial therapy (or on therapy for less than 1 year): approve if the patient meets (A, B, C and D): A) current body mass index greater than or equal to 30 kg/m <sup>2</sup> AND B) patient had a sleep study that shows both (a and b): a) diagnosed with moderate-to-severe OSA, and b) apnea-hypoxia index greater than or equal to 15 events per hour AND C) the patient does not have (a or b): a) Central sleep apnea with percent of central apneas/hypoapneas greater than or equal to 50 percent, or b) Cheyne Stokes respiration AND D) the medication will be used in combination with a reduced calorie diet (e.g. prescriber attestation that patient has received counseling on diet). Obstructive sleep apnea (OSA), moderate to severe, in a patient with obesity, continuation of therapy (on therapy at least 1 year): approve if the patient meets (A, B and C): A) body mass index greater than or equal to 30 kg/m <sup>2</sup> (at baseline, prior to Zepbound), and B) patient has stability in OSA signs or symptoms, according to the prescriber, and C) the medication will be used in combination with a reduced calorie diet (e.g. prescriber attestation that patient has received counseling on diet).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# ZEPOSIA

## Products Affected

- ZEPOSIA
- ZEPOSIA STARTER KIT (28-DAY)
- ZEPOSIA STARTER PACK (7-DAY)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	UC-18 years and older
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	MS-approve. Ulcerative Colitis, initial-approve if the patient has tried TWO of the following: a preferred adalimumab product, a preferred ustekinumab product, a preferred infliximab product, Rinvoq, Skyrizi, Tremfya. Note-a trial of Simponi SC, Entyvio IV/SC, Omvoh IV/SC, a non-preferred adalimumab product, a non-preferred ustekinumab product or a non-preferred infliximab would also count). Cont tx-approve if the patient has been established on Zeposia. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma. Preferred infliximab products include Remicade, Zymfentra. Preferred ustekinumab products include Stelara, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ZEPZELCA

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## Products Affected

- ZEPZELCA

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. Small cell lung cancer-approve.
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-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 meets one of the following: 1) 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), 2) 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 3) 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 Fulphila and Nyvepria and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Ziextenzo.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

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

# ZIIHERA

## Products Affected

- ZIIHERA

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. BILIARY TRACT CANCER - (all of A, B, C, D and E): A. Patient has ONE of the following (i, ii, or iii): i. Gallbladder cancer, OR ii. Intrahepatic cholangiocarcinoma, OR iii. Extrahepatic cholangiocarcinoma, AND B. Patient has unresectable, resected gross residual, or metastatic disease, AND C. The tumor is human epidermal growth factor receptor 2 (HER2) positive with immunohistochemistry score of 3+ (IHC3+) as determined by an approved test, AND D. The medication is used for subsequent therapy, AND E. The medication is used as a single agent.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ZILBRYSQ

## Products Affected

- ZILBRYSQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with another complement inhibitor, a neonatal Fc receptor blocker, or a rituximab Product
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial/continuation)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Initial-6 months, continuation 1 year
<b>Other Criteria</b>	Generalized myasthenia gravis, initial therapy-Approve if the patient meets the following (i, ii, iii and iv): i. Patient has confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis, AND ii. Patient meets both of the following (a and b): a)Myasthenia Gravis Foundation of America classification of II to IV, AND b) Myasthenia Gravis Activities of Daily Living (MG-ADL) score of greater than or equal to 6, AND iii. Patient meets one of the following (a or b): a) Patient received or is currently receiving pyridostigmine, OR b) Patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine, AND iv. Patient has evidence of unresolved symptoms of generalized myasthenia gravis. Note: Evidence of unresolved symptoms of generalized myasthenia gravis includes difficulty swallowing, difficulty breathing, and a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility). Generalized myasthenia gravis, continuation-approve if the patient is continuing to derive benefit from Zilbrysq. Note: Examples of derived benefit include reductions in exacerbations of myasthenia gravis, improvements in speech, swallowing, mobility, and respiratory function.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

PA Criteria	Criteria Details
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 m <sup>2</sup> 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 m <sup>2</sup> 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

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## 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 0.15% CREAM

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## Products Affected

- ZORYVE TOPICAL CREAM 0.15 %

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	ATOPIC DERMATITIS-Try TWO of: pimecrolimus cream (Elidel cream, generics), tacrolimus ointment, Eucrisa, or topical corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No



# ZORYVE CREAM

## Products Affected

- ZORYVE TOPICAL CREAM 0.3 %

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	<p>Plaque Psoriasis: Approve if patient has psoriasis involvement estimated to affect less than or equal to 20 percent of the body surface area and meets (A or B): A) Patient is treating plaque psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia OR B) Meets (i and ii): i) Patient has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid, AND Inadequate efficacy was demonstrated with this topical corticosteroid and ii) Patient has tried at least one topical vitamin D analog, (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 0.064% suspension (Taclonex, generic. Concomitant use of a topical vitamin d analog and a topical corticosteroid would meet the requirement) AND Inadequate efficacy was demonstrated with this topical vitamin D analog.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# ZORYVE FOAM

## Products Affected

- ZORYVE TOPICAL FOAM

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Plaque psoriasis - 12 years and older, Seborrheic dermatitis - 9 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	1 year
Other Criteria	Seborrheic dermatitis-approve if the patient has tried a generic topical corticosteroid or a generic topical antifungal. Note-A trial of a combination product containing a topical antifungal or topical corticosteroid would also count. Plaque psoriasis - approve if pt meets (A and B): A) psoriasis involvement estimated to affect less than or equal to 25 percent of the body surface area, and B) meets (i or ii): i) treating plaque psoriasis affecting one of the following areas: face, eyelids, skin folds, and/or genitalia, or ii) patient has tried one medium, medium-high, high, or super-high potency topical corticosteroid or one topical vitamin D analog or a combination product containing a topical vitamin D analog and topical corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ZTALMY

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## 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 ORAL CAPSULE 20 MG, 25 MG, 30 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Previous treatment with Zurzuvae during the current episode of postpartum depression
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ZYDELIG

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## 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 or Lorbrena prior to approval of Zykadia. NSCLC, ROS1 Rearrangement-approve if the patient has advanced or metastatic disease. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).
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. Peripheral T-Cell Lymphoma.
Part B Prerequisite	No

# ZYMFENTRA

## Products Affected

- ZYMFENTRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist (initial therapy)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	Crohn's Disease, initial therapy-Approve if the patient is currently receiving infliximab intravenous maintenance therapy or will receive induction dosing with an infliximab intravenous product within 3 months of initiating therapy with Zymfentra. Crohn's Disease, continuation-approve if the patient has had a response to therapy. Ulcerative Colitis, initial therapy-Approve if the patient is currently receiving infliximab intravenous maintenance therapy or will receive induction dosing with an infliximab intravenous product within 3 months of initiating therapy with Zymfentra.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# ZYNLONTA

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## 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, HIV-Related B-Cell Lymphoma and post-transplant lymphoproliferative disorder-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, Post-transplant lymphoproliferative disorders
Part B Prerequisite	No

# ZYNYZ

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## 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 locally advanced disease or recurrent regional disease. Anal carcinoma- approve if pt has either locally recurrent persistent disease or metastatic disease AND medication is used for subsequent treatment.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anal carcinoma
Part B Prerequisite	No

# ZYTIGA

## Products Affected

- *abiraterone oral tablet 250 mg, 500 mg*
- *abirtega*
- 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 used concurrently used with a gonadotropin-releasing hormone (GnRH) analog (see Note 1) 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 analog (see Note 1) 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 or ii ): i. abiraterone with prednisone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. 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 prednisone, the medication will be used in combination with external beam radiation therapy and the patient meets one of the following criteria (i or ii): i. abiraterone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer- radical prostatectomy or post radiation therapy-approve if

PA Criteria	Criteria Details
	<p>patient meets (A, B, C and D): A) the medication is used in combination with prednisone, B) meets (i or ii): i) the patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy or ii) PSA recurrence or positive digital rectal examination (DRE) after radiation therapy, C) patient has pelvic recurrence or positive regional lymph nodes, and D) the medication will be used concurrently with GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Salivary Gland Tumors- approve if (A, B and C): A) used in combination with prednisone, B) androgen receptor-positive (AR+) recurrent, unresectable or metastatic tumor, and C) used in combination with a GnRH analog (see Note 1). Note 1: examples of GnRH analogs 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 subcutaneous injection), Orgovyx (relugolix tablets).</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Prostate Cancer-Regional Risk Group, Prostate cancer-very-high-risk group, Prostate cancer- radical prostatectomy or post radiation, Salivary Gland Tumors
<b>Part B Prerequisite</b>	No

## PART B VERSUS PART D

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### Products Affected

- ABRAXANE INTRAVENOUS SUSPENSION FOR RECONSTITUTION 100 MG
- *acetylcysteine solution 100 mg/ml (10 %), 200 mg/ml (20 %)*
- *acyclovir sodium intravenous solution 50 mg/ml*
- ADCETRIS INTRAVENOUS RECON SOLN 50 MG
- ADRIAMYCIN INTRAVENOUS RECON SOLN 50 MG
- AGGRASTAT INTRAVENOUS CONCENTRATE 250 MCG/ML
- AGGRASTAT IN SODIUM CHLORIDE INTRAVENOUS SOLUTION 12.5 MG/250 ML (50 MCG/ML), 5 MG/100 ML (50 MCG/ML)
- *albuterol sulfate inhalation solution for nebulization 0.63 mg/3 ml, 1.25 mg/3 ml, 2.5 mg /3 ml (0.083 %), 2.5 mg/0.5 ml, 5 mg/ml*
- ALIMTA INTRAVENOUS RECON SOLN 100 MG, 500 MG
- ALIQOPA INTRAVENOUS RECON SOLN 60 MG
- AMBISOME INTRAVENOUS SUSPENSION FOR RECONSTITUTION 50 MG
- *amiodarone intravenous solution 50 mg/ml*
- *amphotericin b injection recon soln 50 mg*
- *amphotericin b liposome intravenous suspension for reconstitution 50 mg*
- *aprepitant oral capsule 125 mg, 40 mg, 80 mg*
- *aprepitant oral capsule,dose pack 125 mg (1)- 80 mg (2)*
- *arformoterol inhalation solution for nebulization 15 mcg/2 ml*
- ARRANON INTRAVENOUS SOLUTION 250 MG/50 ML
- *arsenic trioxide intravenous solution 1 mg/ml, 2 mg/ml*
- ASTAGRAF XL ORAL CAPSULE,EXTENDED RELEASE 24HR 0.5 MG, 1 MG, 5 MG
- ATGAM INTRAVENOUS SOLUTION 50 MG/ML
- AVGEMSI INTRAVENOUS SOLUTION 1 GRAM/26.3 ML (38 MG/ML), 2 GRAM/52.6 ML (38 MG/ML)
- AXTLE INTRAVENOUS RECON SOLN 100 MG, 500 MG
- *azacitidine injection recon soln 100 mg*
- AZASAN ORAL TABLET 100 MG, 75 MG
- *azathioprine oral tablet 100 mg, 50 mg, 75 mg*
- *azathioprine sodium injection recon soln 100 mg*
- *baclofen intrathecal solution 10,000 mcg/20ml (500 mcg/ml), 20,000 mcg/20ml (1,000 mcg/ml), 40,000 mcg/20ml (2,000 mcg/ml)*
- *baclofen intrathecal syringe 50 mcg/ml (1 ml)*
- BAVENCIO INTRAVENOUS SOLUTION 20 MG/ML
- BELEODAQ INTRAVENOUS RECON SOLN 500 MG
- *bendamustine intravenous recon soln 100 mg, 25 mg*
- BENDAMUSTINE INTRAVENOUS SOLUTION 25 MG/ML
- BENDEKA INTRAVENOUS SOLUTION 25 MG/ML
- BESPONSA INTRAVENOUS RECON SOLN 0.9 MG (0.25 MG/ML INITIAL)
- BILPREVDA SUBCUTANEOUS SOLUTION 120 MG/1.7 ML (70 MG/ML)
- *bleomycin injection recon soln 15 unit, 30 unit*
- BLINCYTO INTRAVENOUS KIT 35 MCG

- BOMYNTRA SUBCUTANEOUS SOLUTION 120 MG/1.7 ML (70 MG/ML)
- BOMYNTRA SUBCUTANEOUS SYRINGE 120 MG/1.7 ML (70 MG/ML)
- BORTEZOMIB INJECTION RECON SOLN 1 MG, 2.5 MG
- *bortezomib injection recon soln 3.5 mg*
- BORUZU INJECTION SOLUTION 2.5 MG/ML
- BROVANA INHALATION SOLUTION FOR NEBULIZATION 15 MCG/2 ML
- *budesonide inhalation suspension for nebulization 0.25 mg/2 ml, 0.5 mg/2 ml, 1 mg/2 ml*
- *busulfan intravenous solution 60 mg/10 ml*
- BUSULFEX INTRAVENOUS SOLUTION 60 MG/10 ML
- CAMPTOSAR INTRAVENOUS SOLUTION 100 MG/5 ML, 300 MG/15 ML, 40 MG/2 ML
- *carboplatin intravenous solution 10 mg/ml*
- *carmustine intravenous recon soln 100 mg*
- CELLCEPT INTRAVENOUS RECON SOLN 500 MG
- CELLCEPT ORAL CAPSULE 250 MG
- CELLCEPT ORAL SUSPENSION FOR RECONSTITUTION 200 MG/ML
- CELLCEPT ORAL TABLET 500 MG
- *cidofovir intravenous solution 75 mg/ml*
- *cisplatin intravenous solution 1 mg/ml*
- *cladribine intravenous solution 10 mg/10 ml*
- CLINIMIX 5%/D15W SULFITE FREE INTRAVENOUS PARENTERAL SOLUTION 5 %
- CLINIMIX 4.25%/D10W SULF FREE INTRAVENOUS PARENTERAL SOLUTION 4.25 %
- CLINIMIX 4.25%/D5W SULFIT FREE INTRAVENOUS PARENTERAL SOLUTION 4.25 %
- CLINIMIX 5%-D20W(SULFITE-FREE) INTRAVENOUS PARENTERAL SOLUTION 5 %
- CLINIMIX 6%-D5W (SULFITE-FREE) INTRAVENOUS PARENTERAL SOLUTION 6-5 %
- CLINIMIX 8%-D10W(SULFITE-FREE) INTRAVENOUS PARENTERAL SOLUTION 8-10 %
- CLINIMIX 8%-D14W(SULFITE-FREE) INTRAVENOUS PARENTERAL SOLUTION 8-14 %
- CLINIMIX E 2.75%/D5W SULF FREE INTRAVENOUS PARENTERAL SOLUTION 2.75 %
- CLINIMIX E 4.25%/D10W SUL FREE INTRAVENOUS PARENTERAL SOLUTION 4.25 %
- CLINIMIX E 4.25%/D5W SULF FREE INTRAVENOUS PARENTERAL SOLUTION 4.25 %
- CLINIMIX E 5%/D15W SULFIT FREE INTRAVENOUS PARENTERAL SOLUTION 5 %
- CLINIMIX E 5%/D20W SULFIT FREE INTRAVENOUS PARENTERAL SOLUTION 5 %
- CLINIMIX E 8%-D10W SULFITEFREE INTRAVENOUS PARENTERAL SOLUTION 8-10 %
- CLINIMIX E 8%-D14W SULFITEFREE INTRAVENOUS PARENTERAL SOLUTION 8-14 %
- CLINISOL SF 15 % INTRAVENOUS PARENTERAL SOLUTION 15 %
- CLINOLIPID INTRAVENOUS EMULSION 20 %
- *clofarabine intravenous solution 1 mg/ml*
- *cromolyn inhalation solution for nebulization 20 mg/2 ml*
- CUTAQUIG SUBCUTANEOUS SOLUTION 16.5 %
- CUVITRU SUBCUTANEOUS SOLUTION 1 GRAM/5 ML (20 %), 10 GRAM/50 ML (20 %), 2 GRAM/10 ML (20 %), 4 GRAM/20 ML (20 %), 8 GRAM/40 ML (20 %)
- *cyclophosphamide intravenous recon soln 1 gram, 2 gram, 500 mg*

- CYCLOPHOSPHAMIDE INTRAVENOUS SOLUTION 100 MG/ML, 200 MG/ML, 500 MG/ML
- *cyclophosphamide oral capsule 25 mg, 50 mg*
- CYCLOPHOSPHAMIDE ORAL TABLET 25 MG, 50 MG
- *cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg*
- *cyclosporine modified oral solution 100 mg/ml*
- *cyclosporine oral capsule 100 mg, 25 mg*
- CYRAMZA INTRAVENOUS SOLUTION 10 MG/ML
- *cytarabine (pf) injection solution 100 mg/5 ml (20 mg/ml), 2 gram/20 ml (100 mg/ml), 20 mg/ml*
- *cytarabine injection solution 20 mg/ml*
- CYTOGAM INTRAVENOUS SOLUTION 50 MG/ML
- *dacarbazine intravenous recon soln 100 mg, 200 mg*
- *dactinomycin intravenous recon soln 0.5 mg*
- DANYELZA INTRAVENOUS SOLUTION 4 MG/ML
- DARZALEX FASPRO SUBCUTANEOUS SOLUTION 1,800 MG-30,000 UNIT/15 ML
- DARZALEX INTRAVENOUS SOLUTION 20 MG/ML
- *daunorubicin intravenous solution 5 mg/ml*
- *decitabine intravenous recon soln 50 mg*
- *deferoxamine injection recon soln 2 gram, 500 mg*
- DESFERAL INJECTION RECON SOLN 500 MG
- *dexrazoxane hcl intravenous recon soln 250 mg, 500 mg*
- *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)*
- *dobutamine intravenous solution 250 mg/20 ml (12.5 mg/ml)*
- *docetaxel intravenous solution 160 mg/16 ml (10 mg/ml), 160 mg/8 ml (20 mg/ml), 20 mg/2 ml (10 mg/ml), 20 mg/ml (1 ml), 80 mg/4 ml (20 mg/ml), 80 mg/8 ml (10 mg/ml)*
- DOCIVYX INTRAVENOUS SOLUTION 160 MG/16 ML (10 MG/ML), 20 MG/2 ML (10 MG/ML), 80 MG/8 ML (10 MG/ML)
- *dopamine in 5 % dextrose intravenous solution 200 mg/250 ml (800 mcg/ml), 400 mg/250 ml (1,600 mcg/ml), 400 mg/500 ml (800 mcg/ml), 800 mg/250 ml (3,200 mcg/ml), 800 mg/500 ml (1,600 mcg/ml)*
- *dopamine intravenous solution 200 mg/5 ml (40 mg/ml), 400 mg/10 ml (40 mg/ml)*
- DOXIL INTRAVENOUS SUSPENSION 2 MG/ML
- *doxorubicin intravenous recon soln 10 mg, 50 mg*
- *doxorubicin intravenous solution 10 mg/5 ml, 2 mg/ml, 20 mg/10 ml, 50 mg/25 ml*
- *doxorubicin, peg-liposomal intravenous suspension 2 mg/ml*
- *dronabinol oral capsule 10 mg, 2.5 mg, 5 mg*
- DUOPA J-TUBE INTESTINAL PUMP SUSPENSION 4.63-20 MG/ML
- ELLENCE INTRAVENOUS SOLUTION 200 MG/100 ML, 50 MG/25 ML
- ELZONRIS INTRAVENOUS SOLUTION 1,000 MCG/ML
- EMEND ORAL CAPSULE 80 MG
- EMEND ORAL CAPSULE,DOSE PACK 125 MG (1)- 80 MG (2)
- EMEND ORAL SUSPENSION FOR RECONSTITUTION 125 MG (25 MG/ ML FINAL CONC.)
- EMPliciti INTRAVENOUS RECON SOLN 300 MG, 400 MG
- ENGERIX-B (PF) INTRAMUSCULAR SUSPENSION 20 MCG/ML
- ENGERIX-B (PF) INTRAMUSCULAR SYRINGE 20 MCG/ML

- ENGERIX-B PEDIATRIC (PF) INTRAMUSCULAR SYRINGE 10 MCG/0.5 ML
- ENVARSUS XR ORAL TABLET EXTENDED RELEASE 24 HR 0.75 MG, 1 MG, 4 MG
- *epirubicin intravenous solution 200 mg/100 ml*
- *epoprostenol intravenous recon soln 0.5 mg, 1.5 mg*
- ERBITUX INTRAVENOUS SOLUTION 100 MG/50 ML, 200 MG/100 ML
- *eribulin intravenous solution 1 mg/2 ml (0.5 mg/ml)*
- ERWINASE INJECTION RECON SOLN 10,000 UNIT
- ETOPOPHOS INTRAVENOUS RECON SOLN 100 MG
- *etoposide intravenous solution 20 mg/ml*
- *everolimus (immunosuppressive) oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg*
- EVOMELA INTRAVENOUS RECON SOLN 50 MG
- FASLODEX INTRAMUSCULAR SYRINGE 250 MG/5 ML
- FLOLAN INTRAVENOUS RECON SOLN 0.5 MG, 1.5 MG
- *floxuridine injection recon soln 0.5 gram*
- *fludarabine intravenous recon soln 50 mg*
- *fludarabine intravenous solution 50 mg/2 ml*
- *fluorouracil intravenous solution 1 gram/20 ml, 2.5 gram/50 ml, 5 gram/100 ml, 500 mg/10 ml*
- FOLOTYN INTRAVENOUS SOLUTION 20 MG/ML (1 ML), 40 MG/2 ML (20 MG/ML)
- *formoterol fumarate inhalation solution for nebulization 20 mcg/2 ml*
- *foscarnet intravenous solution 24 mg/ml*
- FRINDOVYX INTRAVENOUS SOLUTION 500 MG/ML
- *fulvestrant intramuscular syringe 250 mg/5 ml*
- GABLOFEN INTRATHECAL SOLUTION 10,000 MCG/20ML (500 MCG/ML), 20,000 MCG/20ML (1,000 MCG/ML), 40,000 MCG/20ML (2,000 MCG/ML)
- GABLOFEN INTRATHECAL SYRINGE 10,000 MCG/20ML (500 MCG/ML), 20,000 MCG/20ML (1,000 MCG/ML), 40,000 MCG/20ML (2,000 MCG/ML), 50 MCG/ML (1 ML)
- *ganciclovir sodium intravenous recon soln 500 mg*
- *ganciclovir sodium intravenous solution 50 mg/ml*
- GAZYVA INTRAVENOUS SOLUTION 1,000 MG/40 ML
- *gemcitabine intravenous recon soln 1 gram, 2 gram, 200 mg*
- *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 oral capsule 100 mg, 25 mg*
- *gengraf oral solution 100 mg/ml*
- GRAFAPEX INTRAVENOUS RECON SOLN 1 GRAM, 5 GRAM
- *granisetron hcl oral tablet 1 mg*
- HALAVEN INTRAVENOUS SOLUTION 1 MG/2 ML (0.5 MG/ML)
- HEPLISAV-B (PF) INTRAMUSCULAR SYRINGE 20 MCG/0.5 ML
- HIZENTRA SUBCUTANEOUS SOLUTION 1 GRAM/5 ML (20 %), 10 GRAM/50 ML (20 %), 2 GRAM/10 ML (20 %), 4 GRAM/20 ML (20 %)
- HIZENTRA SUBCUTANEOUS SYRINGE 1 GRAM/5 ML (20 %), 10 GRAM/50 ML (20 %), 2 GRAM/10 ML (20 %), 4 GRAM/20 ML (20 %)
- HYQVIA SUBCUTANEOUS SOLUTION 10 GRAM /100 ML (10 %), 2.5 GRAM /25 ML (10 %), 20 GRAM /200 ML (10 %), 30 GRAM /300 ML (10 %), 5 GRAM /50 ML (10 %)
- IDAMYCIN PFS INTRAVENOUS SOLUTION 1 MG/ML
- *idarubicin intravenous solution 1 mg/ml*



- IFEX INTRAVENOUS RECON SOLN 1 GRAM, 3 GRAM
- *ifosfamide intravenous recon soln 1 gram, 3 gram*
- *ifosfamide intravenous solution 1 gram/20 ml, 3 gram/60 ml*
- IMFINZI INTRAVENOUS SOLUTION 50 MG/ML
- IMURAN ORAL TABLET 50 MG
- INFUMORPH P/F INJECTION SOLUTION 10 MG/ML, 25 MG/ML
- *intralipid intravenous emulsion 20 %*
- INTRALIPID INTRAVENOUS EMULSION 30 %
- *ipratropium bromide inhalation solution 0.02 %*
- *ipratropium-albuterol inhalation solution for nebulization 0.5 mg-3 mg(2.5 mg base)/3 ml*
- *irinotecan intravenous solution 100 mg/5 ml, 300 mg/15 ml, 40 mg/2 ml, 500 mg/25 ml*
- ISTODAX INTRAVENOUS RECON SOLN 10 MG/2 ML
- IVRA INTRAVENOUS SOLUTION 90 MG/ML
- IXEMPRA INTRAVENOUS RECON SOLN 15 MG, 45 MG
- JEVTANA INTRAVENOUS SOLUTION 10 MG/ML (FIRST DILUTION)
- JYLAMVO ORAL SOLUTION 2 MG/ML
- JYNNEOS (PF) SUBCUTANEOUS SUSPENSION 0.5X TO 3.95X 10EXP8 UNIT/0.5
- KABIVEN INTRAVENOUS EMULSION 3.31-10.8-3.9 %
- KHAPZORY INTRAVENOUS RECON SOLN 175 MG
- KIMMTRAK INTRAVENOUS SOLUTION 100 MCG/0.5 ML
- KYPROLIS INTRAVENOUS RECON SOLN 10 MG, 30 MG, 60 MG
- KYXATA INTRAVENOUS SOLUTION 10 MG/ML
- *leucovorin calcium injection recon soln 100 mg, 200 mg, 350 mg, 50 mg, 500 mg*
- *leucovorin calcium injection solution 10 mg/ml*
- *levalbuterol hcl inhalation solution for nebulization 0.31 mg/3 ml, 0.63 mg/3 ml, 1.25 mg/0.5 ml, 1.25 mg/3 ml*
- *levoleucovorin calcium intravenous recon soln 50 mg*
- *levoleucovorin calcium intravenous solution 10 mg/ml*
- MARINOL ORAL CAPSULE 10 MG, 2.5 MG, 5 MG
- MEDROL ORAL TABLET 16 MG, 2 MG, 4 MG, 8 MG
- *melfalan hcl intravenous recon soln 50 mg*
- *mesna intravenous solution 100 mg/ml*
- MESNEX INTRAVENOUS SOLUTION 100 MG/ML
- *methotrexate sodium (pf) injection recon soln 1 gram*
- *methotrexate sodium (pf) injection solution 25 mg/ml*
- *methotrexate sodium injection solution 25 mg/ml*
- *methotrexate sodium oral tablet 2.5 mg*
- *methylprednisolone oral tablet 16 mg, 32 mg, 4 mg, 8 mg*
- *milrinone in 5 % dextrose intravenous piggyback 20 mg/100 ml (200 mcg/ml), 40 mg/200 ml (200 mcg/ml)*
- *milrinone intravenous solution 1 mg/ml*
- *mitomycin intravenous recon soln 20 mg, 40 mg, 5 mg*
- *mitoxantrone intravenous concentrate 2 mg/ml*
- *morphine (pf) intravenous patient control.analgesia soln 30 mg/30 ml (1 mg/ml)*
- MOZOBIL SUBCUTANEOUS SOLUTION 24 MG/1.2 ML (20 MG/ML)
- *mycophenolate mofetil (hcl) intravenous recon soln 500 mg*
- *mycophenolate mofetil oral capsule 250 mg*

- *mycophenolate mofetil oral suspension for reconstitution 200 mg/ml*
- *mycophenolate mofetil oral tablet 500 mg*
- *mycophenolate sodium oral tablet, delayed release (dr/ec) 180 mg, 360 mg*
- MYFORTIC ORAL TABLET, DELAYED RELEASE (DR/EC) 180 MG, 360 MG
- MYHIBBIN ORAL SUSPENSION 200 MG/ML
- MYLOTARG INTRAVENOUS RECON SOLN 4.5 MG (1 MG/ML INITIAL CONC)
- NEBUPENT INHALATION RECON SOLN 300 MG
- *nelarabine intravenous solution 250 mg/50 ml*
- NEORAL ORAL CAPSULE 100 MG, 25 MG
- NEORAL ORAL SOLUTION 100 MG/ML
- NEXTERONE INTRAVENOUS SOLUTION 150 MG/100 ML (1.5 MG/ML), 360 MG/200 ML (1.8 MG/ML)
- NIPENT INTRAVENOUS RECON SOLN 10 MG
- *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 solution 50 mg/10 ml (5 mg/ml)*
- *nitroprusside in 0.9 % nacl intravenous solution 20 mg/100 ml (0.2 mg/ml), 50 mg/100 ml (0.5 mg/ml)*
- NULOJIX INTRAVENOUS RECON SOLN 250 MG
- NUTRILIPID INTRAVENOUS EMULSION 20 %
- OMEGAVEN INTRAVENOUS EMULSION 10 %
- ONCASPAR INJECTION SOLUTION 750 UNIT/ML
- *ondansetron hcl oral solution 4 mg/5 ml*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- ONDANSETRON ORAL TABLET, DISINTEGRATING 16 MG
- *ondansetron oral tablet, disintegrating 4 mg, 8 mg*
- ONIVYDE INTRAVENOUS DISPERSION 4.3 MG/ML
- ORAPRED ODT ORAL TABLET, DISINTEGRATING 10 MG, 15 MG, 30 MG
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- *oxaliplatin intravenous recon soln 100 mg, 50 mg*
- *oxaliplatin intravenous solution 100 mg/20 ml, 200 mg/40 ml, 50 mg/10 ml (5 mg/ml)*
- *paclitaxel intravenous concentrate 6 mg/ml*
- *paclitaxel protein-bound intravenous suspension for reconstitution 100 mg*
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- *pemetrexed disodium intravenous recon soln 1,000 mg, 100 mg, 500 mg*
- PEMETREXED DISODIUM INTRAVENOUS RECON SOLN 750 MG
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- PEMRYDI RTU INTRAVENOUS SOLUTION 10 MG/ML
- *pentamidine inhalation recon soln 300 mg*
- PERFOROMIST INHALATION SOLUTION FOR NEBULIZATION 20 MCG/2 ML
- PERIKABIVEN INTRAVENOUS EMULSION 2.36-7.5-3.5 %
- PERJETA INTRAVENOUS SOLUTION 420 MG/14 ML (30 MG/ML)
- PLENAMINE INTRAVENOUS PARENTERAL SOLUTION 15 %
- *plerixafor subcutaneous solution 24 mg/1.2 ml (20 mg/ml)*

- PRALATREXATE INTRAVENOUS SOLUTION 20 MG/ML (1 ML), 40 MG/2 ML (20 MG/ML)
- *prednisolone oral tablet 5 mg*
- *prednisolone sodium phosphate oral tablet, disintegrating 10 mg, 15 mg, 30 mg*
- *premasol 10 % intravenous parenteral solution 10 %*
- PRIALT INTRATHECAL SOLUTION 100 MCG/ML, 25 MCG/ML
- PROGRAF INTRAVENOUS SOLUTION 5 MG/ML
- PROGRAF ORAL CAPSULE 0.5 MG, 1 MG, 5 MG
- PROGRAF ORAL GRANULES IN PACKET 0.2 MG, 1 MG
- PROSOL 20 % INTRAVENOUS PARENTERAL SOLUTION
- PULMICORT INHALATION SUSPENSION FOR NEBULIZATION 0.25 MG/2 ML, 0.5 MG/2 ML, 1 MG/2 ML
- PULMOZYME INHALATION SOLUTION 1 MG/ML
- RECOMBIVAX HB (PF) INTRAMUSCULAR SUSPENSION 10 MCG/ML, 40 MCG/ML, 5 MCG/0.5 ML
- RECOMBIVAX HB (PF) INTRAMUSCULAR SYRINGE 10 MCG/ML, 5 MCG/0.5 ML
- *romidepsin intravenous recon soln 10 mg/2 ml*
- RYLAZE INTRAMUSCULAR SOLUTION 10 MG/0.5 ML
- SANDIMMUNE INTRAVENOUS SOLUTION 250 MG/5 ML
- SANDIMMUNE ORAL CAPSULE 100 MG, 25 MG
- SIMULECT INTRAVENOUS RECON SOLN 10 MG, 20 MG
- *sirolimus oral solution 1 mg/ml*
- *sirolimus oral tablet 0.5 mg, 1 mg, 2 mg*
- SMOFLIPID INTRAVENOUS EMULSION 20 %
- *sodium nitroprusside intravenous solution 25 mg/ml*
- SYLVANT INTRAVENOUS RECON SOLN 100 MG, 400 MG
- *tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg*
- TECENTRIQ HYBREZA SUBCUTANEOUS SOLUTION 1,875 MG-30,000 UNIT/15 ML
- TECENTRIQ INTRAVENOUS SOLUTION 1,200 MG/20 ML (60 MG/ML), 840 MG/14 ML (60 MG/ML)
- TEMODAR INTRAVENOUS RECON SOLN 100 MG
- *temsirolimus intravenous recon soln 30 mg/3 ml (10 mg/ml) (first)*
- TEPADINA INJECTION RECON SOLN 100 MG, 15 MG
- TEPADINA INJECTION SOLUTION 200 MG
- TEPYLUTE INTRAVENOUS SOLUTION 10 MG/ML
- *thiotepa injection recon soln 100 mg, 15 mg*
- THYMOGLOBULIN INTRAVENOUS RECON SOLN 25 MG
- TICE BCG INTRAVESICAL SUSPENSION FOR RECONSTITUTION 50 MG
- *tirofiban-0.9% sodium chloride intravenous solution 12.5 mg/250 ml (50 mcg/ml), 5 mg/100 ml (50 mcg/ml)*
- *topotecan intravenous recon soln 4 mg*
- *topotecan intravenous solution 4 mg/4 ml (1 mg/ml)*
- TORISEL INTRAVENOUS RECON SOLN 30 MG/3 ML (10 MG/ML) (FIRST)
- *travasol 10 % intravenous parenteral solution 10 %*
- TRAZIMERA INTRAVENOUS RECON SOLN 150 MG, 420 MG
- TREANDA INTRAVENOUS RECON SOLN 100 MG, 25 MG
- TREXALL ORAL TABLET 10 MG, 15 MG, 5 MG, 7.5 MG
- TRISENOX INTRAVENOUS SOLUTION 2 MG/ML

- TROPHAMINE 10 % INTRAVENOUS PARENTERAL SOLUTION 10 %
- TYVASO INHALATION SOLUTION FOR NEBULIZATION 1.74 MG/2.9 ML (0.6 MG/ML)
- TYVASO INSTITUTIONAL START KIT INHALATION SOLUTION FOR NEBULIZATION 1.74 MG/2.9 ML
- TYVASO REFILL KIT INHALATION SOLUTION FOR NEBULIZATION 1.74 MG/2.9 ML (0.6 MG/ML)
- TYVASO STARTER KIT INHALATION SOLUTION FOR NEBULIZATION 1.74 MG/2.9 ML
- UNITUXIN INTRAVENOUS SOLUTION 3.5 MG/ML
- *valrubicin intravesical solution 40 mg/ml*
- VALSTAR INTRAVESICAL SOLUTION 40 MG/ML
- VARUBI ORAL TABLET 90 MG
- VECTIBIX INTRAVENOUS SOLUTION 100 MG/5 ML (20 MG/ML), 400 MG/20 ML (20 MG/ML)
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- *veletri intravenous recon soln 0.5 mg, 1.5 mg*
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- VIDAZA INJECTION RECON SOLN 100 MG
- *vinblastine intravenous solution 1 mg/ml*
- *vincristine intravenous solution 1 mg/ml, 2 mg/2 ml*
- *vinorelbine intravenous solution 10 mg/ml, 50 mg/5 ml*
- VIVIMUSTA INTRAVENOUS SOLUTION 25 MG/ML
- VYXEOS INTRAVENOUS RECON SOLN 44-100 MG
- WYOST SUBCUTANEOUS SOLUTION 120 MG/1.7 ML (70 MG/ML)
- XATMEP ORAL SOLUTION 2.5 MG/ML
- XEMBIFY SUBCUTANEOUS SOLUTION 1 GRAM/5 ML (20 %), 10 GRAM/50 ML (20 %), 2 GRAM/10 ML (20 %), 4 GRAM/20 ML (20 %)
- XGEVA SUBCUTANEOUS SOLUTION 120 MG/1.7 ML (70 MG/ML)
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- YONDELIS INTRAVENOUS RECON SOLN 1 MG
- YUPELRI INHALATION SOLUTION FOR NEBULIZATION 175 MCG/3 ML
- ZALTRAP INTRAVENOUS SOLUTION 100 MG/4 ML (25 MG/ML), 200 MG/8 ML (25 MG/ML)
- ZANOSAR INTRAVENOUS RECON SOLN 1 GRAM
- ZIRABEV INTRAVENOUS SOLUTION 25 MG/ML
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- ZOLEDRONIC AC-MANNITOL-0.9NACL INTRAVENOUS PIGGYBACK 4 MG/100 ML
- ZORTRESS ORAL TABLET 0.25 MG, 0.5 MG, 0.75 MG, 1 MG

## 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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