

# ACTEMRA

## 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

PA Criteria	Criteria Details
	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>	<p>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</p>

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

# ACTIMMUNE

## Products Affected

- ACTIMMUNE

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

## ACYCLOVIR (TOPICAL)

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### Products Affected

- *acyclovir topical ointment*

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

# ADALIMUMAB

## Products Affected

- CYLTEZO(CF) PEN MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML
- 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
- 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
- HUMIRA(CF) PEN (PREFERRED NDCS NDCS STARTING WITH 00074) SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- HUMIRA(CF) PEN CROHNS-UC-HS (PREFERRED NDCS NDCS STARTING WITH 00074)
- HUMIRA(CF) PEN PSOR-UV-ADOL HS (PREFERRED NDCS NDCS STARTING WITH 00074)
- 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

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 -

PA Criteria	Criteria Details
	dermatologist.UV/scleritis-ophthalmologist. Behcet's- rheum, dermat, ophthalmol, gastro, neuro. Sarcoidosis, pulm, ophthalmol, dermat.
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	<p>INITIAL THERAPY: CROHN'S DISEASE (CD): approve. JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA (one of A, B, C, D, or E): A) tried one other systemic therapy (e.g., MTX, sulfasalazine, leflunomide, NSAID), B) tried a biologic (e.g., etanercept, abatacept, infliximab, anakinra, tocilizumab), C) will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide, D) patient has absolute contraindication to MTX, sulfasalazine, or leflunomide, or E) patient has aggressive disease. HIDRADENITIS SUPPURATIVA (HS): tried one other therapy (e.g., intralesional or oral CS, systemic antibiotics, isotretinoin). 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. RHEUMATOID ARTHRITIS (RA): tried one conventional synthetic DMARD for at least 3 months (Note: a 3-month trial of a biologic will also count). ULCERATIVE COLITIS: approve. BEHCET'S DISEASE (A or B): A) tried one conventional therapy (e.g., systemic CS, azathioprine, MTX, CSA, chlorambucil, cyclophosphamide, interferon alfa), or B) has ophthalmic manifestations. SARCOIDOSIS (A and B): A) tried one CS, and B) tried one immunosuppressant (e.g. MTX, mycophenolate mofetil, chlorambucil, thalidomide, infliximab, chloroquine). SCLERITIS: tried one other therapy (e.g. CS, CSA). NON RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation defined as either (A or B): A) C-reactive protein elevated beyond upper limit of normal, or B) sacroiliitis on MRI. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy.</p>
<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

## ADEMPAS

### Products Affected

- ADEMPAS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH and CTEPH- 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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ADSTILADRIN

## Products Affected

- ADSTILADRIN

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

# AKEEGA

## Products Affected

- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prostate cancer- Approve if the patient meets the following (A, B, C, and D): A)Patient has metastatic castration-resistant prostate cancer, AND B)Patient has a BReast CAncer (BRCA) mutation, AND C)The medication is used in combination with prednisone, AND D)Patient meets one of the following (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog, Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), and Orgovyx (relugolix tablets).OR ii. Patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ALDURAZYME

## Products Affected

- ALDURAZYME

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

# ALECENSA

## Products Affected

- ALECENSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Pediatric diffuse high grade glioma- less than or equal to 21 years old, All others- 18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<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*

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

## ALPHA 1 PROTEINASE INHIBITORS

### Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	ALK status
<b>Age Restrictions</b>	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 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 Lorbrina prior to approval of Alunbrig. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT), Peripheral T-Cell Lymphoma
<b>Part B Prerequisite</b>	No

# ANKTIVA

## Products Affected

- ANKTIVA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist (initial/maintenance therapy)
<b>Coverage Duration</b>	Initial-6 months, Maintenance-3 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## ANTIBIOTICS (IV)

### 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
- azithromycin intravenous
- aztreonam
- BICILLIN L-A
- cefoxitin
- cefoxitin in dextrose, iso-osm
- ceftazidime
- cefuroxime sodium injection recon soln 750 mg
- cefuroxime sodium intravenous
- ciprofloxacin in 5 % dextrose
- clindamycin in 5 % dextrose
- clindamycin phosphate injection
- colistin (colistimethate na)
- doxy-100
- doxycycline hyclate intravenous
- ertapenem
- gentamicin in nacl (iso-osm) intravenous piggyback 100 mg/100 ml, 60 mg/50 ml, 80 mg/100 ml, 80 mg/50 ml
- gentamicin injection
- gentamicin sulfate (ped) (pf)
- imipenem-cilastatin
- levofloxacin in d5w
- levofloxacin intravenous
- lincomycin
- linezolid in dextrose 5%
- linezolid-0.9% sodium chloride
- meropenem intravenous recon soln 1 gram, 2 gram, 500 mg
- metro i.v.
- metronidazole in nacl (iso-os)
- moxifloxacin-sod.chloride(iso)
- nafcillin in dextrose iso-osm intravenous piggyback 2 gram/100 ml
- nafcillin injection
- oxacillin
- oxacillin in dextrose(iso-osm) intravenous piggyback 2 gram/50 ml
- penicillin g potassium
- penicillin g sodium
- pfizerpen-g
- STREPTOMYCIN
- sulfamethoxazole-trimethoprim intravenous
- tazicef
- TEFLARO
- tigecycline
- tobramycin sulfate injection recon soln
- tobramycin sulfate injection solution
- VANCOMYCIN IN 0.9 % SODIUM CHL INTRAVENOUS PIGGYBACK 1 GRAM/200 ML, 500 MG/100 ML, 750 MG/150 ML
- vancomycin intravenous recon soln 1,000 mg, 10 gram, 5 gram, 500 mg, 750 mg

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 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

## ANTIFUNGALS (IV)

### Products Affected

- *fluconazole in nacl (iso-osm) intravenous piggyback 200 mg/100 ml, 400 mg/200 ml*
- *voriconazole*
- *voriconazole-hpbc*

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

# ARCALYST

## Products Affected

- ARCALYST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent biologic therapy
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age.
<b>Prescriber Restrictions</b>	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
<b>Coverage Duration</b>	CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ARIKAYCE

## Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous medication history (as described in Other Criteria field)
<b>Age Restrictions</b>	MAC-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<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>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ASPARLAS

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## Products Affected

- ASPARLAS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	1 month to 21 years
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# AUBAGIO

## Products Affected

- *teriflunomide*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of teriflunomide with other disease-modifying agents used for multiple sclerosis (MS)
<b>Required Medical Information</b>	Relapsing form of 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>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# AUGTYRO

## Products Affected

- AUGTYRO ORAL CAPSULE 160 MG, 40 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	NSCLC - 18 and older, Solid tumors - 12 and older, Pediatric Diffuse High-Grade Glioma-less than 18
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pediatric Diffuse High-Grade Gliomas
<b>Part B Prerequisite</b>	No

# AUSTEDO

## 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

### Products Affected

- AVMAPKI-FAKZYNJA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Fallopian Tube or Primary Peritoneal Cancer
<b>Part B Prerequisite</b>	No

# AVONEX

## 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

# AYVAKIT

## Products Affected

- AYVAKIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myeloid/Lymphoid neoplasms with Eosinophilia
<b>Part B Prerequisite</b>	No

# BALVERSA

## Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies, test results
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 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.,

PA Criteria	Criteria Details
	prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to 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.,

PA Criteria	Criteria Details
	prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to 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

# 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

### Products Affected

- BETASERON SUBCUTANEOUS KIT

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

## BEXAROTENE (ORAL)

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### Products Affected

- *bexarotene*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

## BEXAROTENE (TOPICAL)

### Products Affected

- bexarotene*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Adult T-Cell Leukemia/Lymphoma, Primary Cutaneous B-Cell Lymphoma
<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
<b>Exclusion Criteria</b>	Concurrent use with other medications for Osteoporosis
<b>Required Medical Information</b>	Diagnosis, test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<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 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.

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

## BOSENTAN/AMBRISENTAN

### Products Affected

- *ambrisentan*
- *bosentan oral tablet*

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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan)
<b>Part B Prerequisite</b>	No

# BOSULIF

## Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

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

# BRAFTOVI

## Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, BRAF V600 status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Appendiceal adenocarcinoma

PA Criteria	Criteria Details
Part B Prerequisite	No

## BRIUMVI

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### Products Affected

- BRIUMVI

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 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 MS.
<b>Coverage Duration</b>	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

# BRUKINSA

## Products Affected

- BRUKINSA ORAL CAPSULE
- BRUKINSA ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Hairy Cell Leukemia
<b>Part B Prerequisite</b>	No

# BYOOVIZ

## Products Affected

- BYOOVIZ

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

## C1 ESTERASE INHIBITORS

### Products Affected

- CINRYZE

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

# CABLIVI

## Products Affected

- CABLIVI INJECTION KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, concurrent medications
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist
<b>Coverage Duration</b>	Approve for 12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CABOMETYX

## Products Affected

- CABOMETYX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, histology, RET gene rearrangement status for NSCLC
<b>Age Restrictions</b>	Neuroendocrine tumor/Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<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.



PA Criteria	Criteria Details
Part B Prerequisite	No

# CAMZYOS

## Products Affected

- CAMZYOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial and continuation)
<b>Prescriber Restrictions</b>	Prescribed by a cardiologist (initial and continuation)
<b>Coverage Duration</b>	Initial-8 months, continuation- 1 year
<b>Other Criteria</b>	<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):</p>

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

# CAPRELSA

## Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	MTC - approve. DTC - approve if refractory to radioactive iodine therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma.
Part B Prerequisite	No

## CARGLUMIC ACID

### Products Affected

- carglumic acid*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases
<b>Coverage Duration</b>	NAGS-Pt meets criteria no genetic test - 3mo. Pt had genetic test - 12mo, other-approve 7 days
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (generic carglumic acid)
<b>Part B Prerequisite</b>	No

# CAYSTON

## Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist, 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 Pseudomonas aeruginosa in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# CEPROTIN

## Products Affected

- CEPROTIN (BLUE BAR)
- CEPROTIN (GREEN BAR)

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

# CHEMET

## Products Affected

- CHEMET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Blood lead level
<b>Age Restrictions</b>	Approve in patients between the age of 12 months and 18 years
<b>Prescriber Restrictions</b>	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)
<b>Coverage Duration</b>	Approve for 2 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CIMERLI

## Products Affected

- CIMERLI

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

# CINACALCET

## Products Affected

- *cinacalcet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	hyperparathyroidism in post-renal transplant patients
<b>Part B Prerequisite</b>	No

# CLOBAZAM

## Products Affected

- *clobazam oral suspension*
- *clobazam 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
<b>Exclusion Criteria</b>	Use in patients for infertility
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Male hypogonadism
<b>Part B Prerequisite</b>	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</p>

PA Criteria	Criteria Details
	(rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin). Post-transplant lymphoproliferative disorders- approve if the patient has received two or more lines of systemic therapy, the medication will be given as a single agent and the patient has or will receive pretreatment with obinutuzmab intravenous infusion before the first dose of Columvi. Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine).
<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
<b>Exclusion Criteria</b>	N/A
<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>	MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and oncocytic) 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma
<b>Part B Prerequisite</b>	No

# COPIKTRA

## Products Affected

- COPIKTRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	T-cell Lymphoma
<b>Part B Prerequisite</b>	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

PA Criteria	Criteria Details
Part B Prerequisite	No

## COSENTYX IV

### Products Affected

- COSENTYX INTRAVENOUS

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 and older (initial therapy)
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# COTELLIC

## Products Affected

- COTELLIC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Central Nervous System Cancer

PA Criteria	Criteria Details
Part B Prerequisite	No

## CRESEMBA (ORAL)

### Products Affected

- CRESEMBA ORAL

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

# CRYSVITA

## Products Affected

- CRYSVITA

PA Criteria	Criteria Details
<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>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

## CYSTEAMINE (OPHTHALMIC)

### Products Affected

- CYSTARAN

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

## CYSTEAMINE (ORAL)

### Products Affected

- CYSTAGON

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of Cystagon and Procysbi
<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 nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DALFAMPRIDINE

## Products Affected

- *dalfampridine*

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 (initial and continuation therapy)
<b>Prescriber Restrictions</b>	MS. If prescribed by, or in consultation with, a neurologist or MS specialist (initial and continuation).
<b>Coverage Duration</b>	Initial-4months, Continuation-1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DANZITEN

## Products Affected

- DANZITEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	ALL - 15 years and older, GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Acute lymphoblastic leukemia, Pigmented villonodular synovitis/Tenosynovial giant cell tumor, GIST, cutaneous melanoma and myeloid/lymphoid neoplasms with eosinophilia
<b>Part B Prerequisite</b>	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

PA Criteria	Criteria Details
Part B Prerequisite	No

# DAURISMO

## Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medications that will be used in combination, comorbidities
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	AML - approve if Daurismo will be used in combination with cytarabine.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## DEFERASIROX

### Products Affected

- *deferasirox oral tablet*

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

# DEFERIPRONE

## Products Affected

- *deferiprone*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Serum ferritin level
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias-Initial therapy - approve. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

## DIABETIC SUPPLY - ALCOHOL PADS

### 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

### 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
- 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.
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

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

# DIACOMIT

## Products Affected

- DIACOMIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of diagnosis.
<b>Age Restrictions</b>	6 months and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an neurologist (initial therapy)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DIMETHYL FUMARATE

## Products Affected

- *dimethyl fumarate oral capsule, delayed release(dr/ec) 120 mg, 120 mg (14)- 240 mg (46), 240 mg*

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

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>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## DUAL OREXIN RECEPTOR ANTAGONIST

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### Products Affected

- BELSOMRA

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,

PA Criteria	Criteria Details
	asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Esophagitis-prescr/consult-allergist or gastro. COPD-prescribed by or in consultation with an allergist, immunologist, or pulmonologist. BP-prescr/consult with derm
<b>Coverage Duration</b>	AD-Init-4mo, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/PN/COPD/CSU/BP-init-6 mo, cont 1 yr
<b>Other Criteria</b>	<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, pruritus, or nodular lesion size.</p>

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

# ELAHERE

## Products Affected

- ELAHERE

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

## ELAPRASE

### Products Affected

- ELAPRASE

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

# ELREXFIO

## Products Affected

- ELREXFIO

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

# EMGALITY

## Products Affected

- EMGALITY PEN
- EMGALITY SUBCUTANEOUS SYRINGE 120 MG/ML

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

## EMRELIS

### Products Affected

- EMRELIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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)
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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-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,

PA Criteria	Criteria Details
	immunosuppressant, interferon alfa, mycophenolate), adalimumab, or 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

### Products Affected

- 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

# ENTYVIO

## 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

# EPIDIOLEX

## Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies
<b>Age Restrictions</b>	Patients 1 year 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>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# EPKINLY

## Products Affected

- EPKINLY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<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. 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.
<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

# EPOETIN ALFA

## Products Affected

- PROCRIT
- RETACRIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	MDS anemia = 18 years of age and older
<b>Prescriber Restrictions</b>	MDS anemia/myelofibrosis, prescribed by or in consultation with, a hematologist or oncologist.
<b>Coverage Duration</b>	Chemo-6m,Transfus-1m,Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr
<b>Other Criteria</b>	<p>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</p>

PA Criteria	Criteria Details
	equal to 12g/dL. 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

## 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>	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

### Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

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

# ERLOTINIB

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<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>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma.
<b>Part B Prerequisite</b>	No

# EVEROLIMUS

## Products Affected

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

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

PA Criteria	Criteria Details
	<p>WM/LPL - approve if pt has progressive or relapsed disease or if pt has not responded to primary therapy. Thyroid Carcinoma, differentiated-approve if pt is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if everolimus will be used in combo with letrozole. GIST-approve if pt has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock or imatinib AND there is confirmation that 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-approve if pt has perivascular epithelioid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangiomyomatosis. Classic hodgkin lymphoma-approve if pt has relapsed or refractory disease AND has tried at least three prior lines of chemotherapy. Histiocytic neoplasm-approve if pt has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis. Patient must also have PIK3CA mutation. Meningioma-approve if pt has recurrent or progressive disease AND pt has surgically inaccessible disease and radiation therapy is not possible AND medication will be used in combination with a somatostatin analogue. Uterine Sarcoma-approve if the patient has advanced, recurrent, metastatic, or inoperable disease, AND has a perivascular epithelioid cell tumor (PEComa), AND has tried at least one systemic regimen. Note: Examples of systemic regimen include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine.</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

# EYLEA

## Products Affected

- EYLEA

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

# FABRAZYME

## Products Affected

- FABRAZYME

PA Criteria	Criteria Details
<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

# FINGOLIMOD

## Products Affected

- *fingolimod*

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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an neurologist (initial therapy)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## FIRMAGON

### Products Affected

- FIRMAGON KIT W DILUENT SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Patients new to therapy, are required to try Eligard or Orgovyx prior to approval of Firmagon.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# FOTIVDA

## Products Affected

- FOTIVDA

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

# FRUZAQLA

## Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Appendiceal cancer

PA Criteria	Criteria Details
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

# GATTEX

## Products Affected

- GATTEX 30-VIAL
- GATTEX ONE-VIAL

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

# GAVRETO

## Products Affected

- GAVRETO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	NSCLC-18 years and older, thyroid cancer-12 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Medullary Thyroid Cancer, Anaplastic Thyroid Cancer
<b>Part B Prerequisite</b>	No

## GEFITINIB

### Products Affected

- *gefitinib*

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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For NSCLC - EGFR exon deletions or mutations or if NSCLC is squamous cell type
<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>	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)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Head and neck cancer
<b>Part B Prerequisite</b>	Yes

# GLATIRAMER

## Products Affected

- *glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml*
- *glatopa subcutaneous syringe 20 mg/ml, 40 mg/ml*

PA Criteria	Criteria Details
<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>	N/A
<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

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

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

## GNRH AGONIST IMPLANTS

### Products Affected

- ZOLADEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Endometriosis-18 years and older
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Abnormal uterine bleeding-2 months, Endometriosis-6 months, all other dx-1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Zoladex 3.6mg only: head and neck cancer - salivary gland tumors, Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer, and Uterine Cancer
<b>Part B Prerequisite</b>	No

# GOMEKLI

## 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 - ONCOLOGY

## Products Affected

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)
- *leuprolide subcutaneous kit*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Head and neck cancer- salivary gland tumors (Eligard only)
<b>Part B Prerequisite</b>	No

# GROWTH HORMONES

## Products Affected

- OMNITROPE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>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 and results are 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>
<b>Age Restrictions</b>	ISS 5 y/o or older, SGA 2 y/o or older, SBS 18 y/o or older
<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, others 12 mos
<b>Other Criteria</b>	GHD initial in adults and adolescents 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple

PA Criteria	Criteria Details
	<p>hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. has known perinatal insults, 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 is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine test with peak of less than or equal to 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 AND if a transitional adolescent must be off tx for at least one month before retesting. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal to 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - prescriber confirms response to therapy. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy. Cont Tx for CKD, Noonan, PW in child/adoles, 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.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Short bowel syndrome

PA Criteria	Criteria Details
Part B Prerequisite	No

# HERNEXEOS

## Products Affected

- HERNEXEOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	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).
<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

- *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*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Procedure-related sedation = 1mo. All other conditions = 12 months.
<b>Other Criteria</b>	All medically accepted indications other than insomnia, approve if the physician has assessed risk versus benefit in using the High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy. Insomnia, may approve lorazepam if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon and the physician has assessed risk versus benefit in using the HRM in this patient and has confirmed that he/she would still like initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## HIGH RISK MEDICATIONS - BENZTROPINE

### Products Affected

- *benztropine oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

### Products Affected

- *cyclobenzaprine oral tablet 10 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	The physician has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

## Products Affected

- *hydroxyzine hcl oral tablet*
- *promethazine oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. Approve hydroxyzine hydrochloride if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval of promethazine and hydroxyzine, approve if the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## HIGH RISK MEDICATIONS - PHENOBARBITAL

### Products Affected

- *phenobarbital*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coverage is not provided for use in sedation/insomnia.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For the treatment of seizures, approve only if the patient is currently taking phenobarbital.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## HIGH RISK MEDICATIONS- ESTROGENS

### Products Affected

- *abigale*
- *abigale lo*
- *dotti*
- *estradiol oral*
- *estradiol transdermal patch semiweekly*
- *estradiol transdermal patch weekly*
- *estradiol-norethindrone acet*
- *fyavolv*
- *jinteli*
- *lyllana*
- *mimvey*
- *norethindrone ac-eth estradiol oral tablet*  
*0.5-2.5 mg-mcg, 1-5 mg-mcg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Previous medication use
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	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 or estradiol valerate. For prophylaxis of Postmenopausal Osteoporosis, approve if the patient has had a trial of one of the following (brand or generic): alendronate, ibandronate, risidronate or Raloxifene. The physician has assessed risk versus benefit in using this High Risk medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# IBRANCE

## Products Affected

- IBRANCE

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>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Liposarcoma
Part B Prerequisite	No

# IBTROZI

## 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

- *icatibant*
- *sajazir*

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

# ICLUSIG

## Products Affected

- ICLUSIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
<b>Age Restrictions</b>	All indications except ALL - 18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia
<b>Part B Prerequisite</b>	No

## IDHIFA

### Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	IDH2-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	AML - approve if the patient is IDH2-mutation status positive as detected by an approved test
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ILARIS

## Products Affected

- ILARIS (PF)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	When used in combination with concurrent biologic therapy (e.g. TNF antagonists, etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or riloncept.
<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

PA Criteria	Criteria Details
	<p>combination with colchicine, unless colchicine is contraindicated or not tolerated, AND 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 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

# IMATINIB

## Products Affected

- *imatinib oral tablet 100 mg, 400 mg*
- IMKELDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
<b>Age Restrictions</b>	ASM, DFSP, HES, MDS/MPD/Myeloid/Lymphoid Neoplasms/Kaposi Sarcoma/Cutaneous Melanoma-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<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

PA Criteria	Criteria Details
	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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	GVHD-1 year and older, other-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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]).</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma

PA Criteria	Criteria Details
Part B Prerequisite	No

# IMDELLTRA

## Products Affected

- IMDELLTRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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</p>

PA Criteria	Criteria Details
	<p>positive, OR (2) NTRK1/2/3 gene fusion positive, OR (3) MET exon 14 skipping mutation positive, OR (4) RET rearrangement positive, AND b) Imjudo is used as first-line or subsequent therapy, OR iv. Patient meets ALL of the following (a, b, and c): a) The tumor is positive for ONE of the following [(1), (2), (3), or (4)]: (1) EGFR exon 19 deletion or exon 21 L858R mutation positive, OR (2) EGFR S768I, L861Q, and/or G719X mutation positive, OR (3) ALK rearrangement positive, OR (4) ROS1 rearrangement, AND b) The patient has received targeted drug therapy for the specific mutation-Note: Examples of targeted drug therapy include Gilotrif (afatinib tablets), Tagrisso (osimertinib tablets), erlotinib, Iressa (gefitinib tablets), Xalkori (crizotinib capsules), Zykadia (ceritinib capsules), Alecensa (alectinib capsules), Alunbrig (brigatinib tablets), Lorbrina (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

# INBRIJA

## Products Affected

- INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Asthma, COPD, other chronic underlying lung disease
<b>Required Medical Information</b>	Diagnosis, 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
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient is currently taking carbidopa-levodopa and is experiencing off episodes.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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,

PA Criteria	Criteria Details
	<p>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., 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>
<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

# INJECTABLE TESTOSTERONE PRODUCTS

## Products Affected

- *testosterone cypionate*
- *testosterone enanthate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, lab results
<b>Age Restrictions</b>	Delayed puberty or induction of puberty in males-14 years and older, 12 years and older (testosterone cypionate)
<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>	Delayed puberty or induction of puberty in males-6 months, all others-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 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,

PA Criteria	Criteria Details
	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

# INLYTA

## Products Affected

- INLYTA ORAL TABLET 1 MG, 5 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>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma, Soft tissue sarcoma
<b>Part B Prerequisite</b>	No

# INQOVI

## 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
<b>Exclusion Criteria</b>	N/A
<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>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myeloid/Lymphoid Neoplasms with Eosinophilia, accelerated or blast phase myeloproliferative neoplasm
<b>Part B Prerequisite</b>	No

# ITOVEBI

## Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	<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>
<b>Indications</b>	All FDA-approved Indications.

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

## IVERMECTIN (ORAL)

### Products Affected

- *ivermectin oral tablet 3 mg, 6 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, Mansonella ozzardi infection, Mansonella streptocerca infection, Pediculosis, Scabies. Trichuriasis, Wucheria bancrofti infection
<b>Part B Prerequisite</b>	No

## IVIG

### Products Affected

- PRIVIGEN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Part B versus D determination per CMS guidance to establish if drug used for PID in pt's home.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# IWILFIN

## Products Affected

- IWILFIN

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

# JAKAFI

## Products Affected

- JAKAFI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	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
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.

PA Criteria	Criteria Details
	Accelerated or blast phase myeloproliferative neoplasm-approve if pt has at least one disease-related symptom (examples: fatigue, fever, night sweats, 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</p>

PA Criteria	Criteria Details
	(zanubrutinib capsules). Richter's Transformation to DLBCL- pt has tried at least one chemotherapy regimen or is not a candidate for a chemotherapy 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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<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. 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Small Bowel Adenocarcinoma, Colon, Rectal or Appendiceal Cancer
Part B Prerequisite	No

# JYNARQUE

## Products Affected

- *tolvaptan (polycystic kidney dis) oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient is currently receiving another tolvaptan product.
<b>Required Medical Information</b>	Diagnosis, renal function
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist
<b>Coverage Duration</b>	1 year (initial and continuation)
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# KADCYLA

## Products Affected

- KADCYLA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Breast Cancer-Recurrent/metastatic-1 yr, Breast Cancer-Adjuvant tx-approve 1 yr total, other-1yr
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-small cell lung cancer (NSCLC), Salivary gland tumor
<b>Part B Prerequisite</b>	No

# KALYDECO

## Products Affected

- KALYDECO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with Orkambi, Trikafta or Symdeko
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	1 month 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 - 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# KANUMA

## Products Affected

- KANUMA

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

# KERENDIA

## Products Affected

- KERENDIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with spironolactone or eplerenone
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial and continuation therapy)
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<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.</p> <p>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.</p> <p>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</p>

PA Criteria	Criteria Details
	<p>(dapagliflozin tabs, authorized generic) Inpefa (sotagliflozin tabs), or Jardiance (empagliflozin tabs) OR has contraindication or has experienced 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.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## KESIMPTA

### 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

# KEYTRUDA

## Products Affected

- KEYTRUDA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	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)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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
<b>Part B Prerequisite</b>	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	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 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali

PA Criteria	Criteria Details
	Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole. Endometrial cancer - approve if pt meets all of (A, 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

# KORLYM

## Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior surgeries
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# KOSELUGO

## Products Affected

- KOSELUGO ORAL CAPSULE

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):</p> <p>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>

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<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 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)</p>

PA Criteria	Criteria Details
	<p>previously treated with at least one systemic regimen. Pancreatic adenocarcinoma- approve if (A and B): A) KRAS G12C mutation-positive 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.</p>
<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

# LANREOTIDE

## Products Affected

- lanreotide subcutaneous syringe 120 mg/0.5 ml
- SOMATULINE DEPOT SUBCUTANEOUS SYRINGE 60 MG/0.2 ML, 90 MG/0.3 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous treatments/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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-approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pheochromocytoma/paraganglioma

PA Criteria	Criteria Details
Part B Prerequisite	No

# LAPATINIB

## Products Affected

- *lapatinib*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which lapatinib is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Bone cancer-chordoma, colon or rectal cancer, breast cancer in pre/perimenopausal women and men
Part B Prerequisite	Yes

# LAZCLUZE

## Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

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

# LEDIPASVIR/SOFOSBUVIR

## Products Affected

- LEDIPASVIR-SOFOSBUVIR

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>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<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

# LENALIDOMIDE

## Products Affected

- *lenalidomide*
- REVLIMID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis and previous therapies or drug regimens tried.
<b>Age Restrictions</b>	18 years and older (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma)
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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

PA Criteria	Criteria Details
	or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide is used in combination with dexamethasone. Histiocytic 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
<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>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

PA Criteria	Criteria Details
	medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy. 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

# LIBTAYO

## Products Affected

- LIBTAYO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous surgeries or radiation
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<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. 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

PA Criteria	Criteria Details
	received targeted drug therapy for the specific mutation. Cervical cancer- approve if pt has local or regional recurrence or distant metastatic disease AND this medication is used as subsequent therapy. Vulvar cancer- approve if pt has advanced, recurrent, or metastatic disease AND this medication is used as subsequent therapy. 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

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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 12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Diabetic neuropathic pain, chronic back pain
<b>Part B Prerequisite</b>	No

# LIVTENCITY

## Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with ganciclovir or valganciclovir
<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 hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center.
<b>Coverage Duration</b>	2 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LONG ACTING OPIOIDS

## Products Affected

- *hydromorphone oral tablet extended release 24 hr*
- *methadone intensol*
- *methadone oral concentrate*
- *methadone oral solution 10 mg/5 ml, 5 mg/5 ml*
- *methadone oral tablet 10 mg, 5 mg*
- *methadose oral concentrate*
- *morphine oral tablet extended release*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute (ie, non-chronic) pain
<b>Required Medical Information</b>	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, in hospice, sickle cell disease or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.

<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

# LONSURF

## Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Gastric or Gastroesophageal Junction Adenocarcinoma, approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma. Colon and rectal cancer-approve per labeling if the patient has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and 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</p>

PA Criteria	Criteria Details
	deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) 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

PA Criteria	Criteria Details
Part B Prerequisite	No

## LUMAKRAS

### Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 240 MG, 320 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<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>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma

PA Criteria	Criteria Details
Part B Prerequisite	No

# LUMIZYME

## Products Affected

- LUMIZYME

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

# LUNSUMIO

## Products Affected

- LUNSUMIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	B-Cell Lymphoma

PA Criteria	Criteria Details
Part B Prerequisite	No

# LUPRON DEPOT

## Products Affected

- LUPRON DEPOT

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 Depot 7.5mg, 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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<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. 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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LYNPARZA

## Products Affected

- LYNPARZA

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>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

PA Criteria	Criteria Details
	<p>resistant-approve if the patient has metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or the pateint has had a bilateral orchiectomy, and the patient meets either (i or ii): i) the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test and the patient has been previously treated with at least one androgen receptor directed therapy or ii) the patient has a BRCA mutation and the medication is used in combination with abiraterone plus one of prednisone or prednisolone. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried at least one systemic regimen.</p>
<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

## 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

# MAVYRET

## Products Affected

- MAVYRET ORAL PELLETS IN PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	Chronic HCV- Criteria will be applied consistent with AASLD/IDSA guidance, Acute HCV-8 weeks
<b>Other Criteria</b>	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.
<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

# MEGESTROL

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coverage is not provided for weight gain for cosmetic reasons.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<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

# MEKINIST

## Products Affected

- MEKINIST ORAL RECON SOLN
- MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations
<b>Age Restrictions</b>	1 year and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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 positive 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

PA Criteria	Criteria Details
	<p>progressive disease for one of the following conditions (a, b, c or d): a) glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma OR iii. Melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Tafinlar (dabrafenib). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR patient has Erdheim Chester disease or Rosai-Dorfman disease. Metastatic or Solid Tumors-Approve if the patient meets the following (A, B, and C): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafinlar (dabrafenib capsules), AND C) Patient has no satisfactory alternative treatment options. 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 Tafinlar. Small bowel adenocarcinoma, approve if pt has BRAF V600E mutation-positive advanced or metastatic disease and this will be used with Tafinlar 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

## Products Affected

- MEKTOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, BRAF V600 status, concomitant medications
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Histiocytic Neoplasms
<b>Part B Prerequisite</b>	No

# MEMANTINE

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Indication for which memantine is being prescribed.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with mild to moderate vascular dementia.
<b>Part B Prerequisite</b>	No

## MEPSEVII

### Products Affected

- MEPSEVII

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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 beta-glucuronidase activity in leukocytes, fibroblasts, or serum OR has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic glucuronidase gene variants.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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

## MODAFINIL/ARMODAFINIL

### Products Affected

- *armodafinil*
- *modafinil 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 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

## Products Affected

- MODEYSO

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

# MONJUVI

## Products Affected

- MONJUVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<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. 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	B-Cell Lymphoma
<b>Part B Prerequisite</b>	No

# MYFEMBREE

## Products Affected

- MYFEMBREE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, test results
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Fibroids-Prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health
<b>Coverage Duration</b>	24 months of total therapy between Myfembree or Oriahnn
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NAGLAZYME

## Products Affected

- NAGLAZYME

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

# NAYZILAM

## Products Affected

- NAYZILAM

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

## NERLYNX

### Products Affected

- NERLYNX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Stage of cancer, HER2 status, previous or current medications tried
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Adjuvant tx-Approve for 1 year (total), advanced or metastatic disease-1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NILUTAMIDE

## Products Affected

- *nilutamide*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	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
<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>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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
<b>Part B Prerequisite</b>	Yes

# NITISINONE

## Products Affected

- nitisinone*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of therapy with nitisinone products
<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>	1 year
<b>Other Criteria</b>	Hereditary Tyrosinemia, 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NIVESTYM

## Products Affected

- NIVESTYM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT,Radiation-1 mo
<b>Other Criteria</b>	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

<b>PA Criteria</b>	<b>Criteria Details</b>
	factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [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

- testosterone transdermal gel 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)
- testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %)
- testosterone transdermal solution in metered pump w/app
- testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram),

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 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-

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

# NUBEQA

## Products Affected

- NUBEQA

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

# NUEDEXTA

## 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

# NUPLAZID

## Products Affected

- NUPLAZID

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

# NURTEC

## Products Affected

- NURTEC ODT

PA Criteria	Criteria Details
<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

# NYVEPRIA

## Products Affected

- NYVEPRIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Cancer pts receiving chemo-6 mo. PBPC-1 mo
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients undergoing PBPC collection and therapy

PA Criteria	Criteria Details
Part B Prerequisite	No

# OCTREOTIDE INJECTABLE

## Products Affected

- *octreotide acetate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-presc/consult with oncologist. Diarrhea assoc w chemo-presc/consult with oncologist/gastro. Small bowel bleed/angiodysplasia-presc/consult gastroenterologist.
<b>Coverage Duration</b>	Enterocutaneous fistula/diarrhea w/chemo-3 mos, other 1 yr
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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

## ODOMZO

### Products Affected

- ODOMZO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	BCC - Must not have had disease progression while on Erivedge (vismodegib).
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Metastatic BCC, diffuse basal cell carcinoma formation
<b>Part B Prerequisite</b>	No

## OFEV

### Products Affected

- OFEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OGSIVEO

## 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

## OJEMDA

### 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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Accelerated or blast phase myeloproliferative neoplasm
<b>Part B Prerequisite</b>	No

# ONUREG

## Products Affected

- ONUREG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Peripheral T-cell lymphoma
<b>Part B Prerequisite</b>	No

# OPDIVO

## Products Affected

- OPDIVO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	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
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Adjuvant treatment of melanoma-approve up to 1 year total, all other dx-1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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
<b>Part B Prerequisite</b>	No

# OPDIVO QVANTIG

## Products Affected

- OPDIVO QVANTIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (all diagnoses except gestational trophoblastic neoplasia, Kaposi sarcoma)
<b>Prescriber Restrictions</b>	Prescribed by or on consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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
<b>Part B Prerequisite</b>	No

# OPDUALAG

## Products Affected

- OPDUALAG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	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

# OPSUMIT

## Products Affected

- OPSUMIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	PAH WHO group, right heart catheterization
<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>	Authorization will be for 1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OPSYNVI

## Products Affected

- OPSYNVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with guanylate cyclase stimulators
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Pulmonary arterial hypertension (PAH) WHO Group 1-approve if patient has had a right-heart catheterization to confirm the diagnosis.
<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.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	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

# ORKAMBI

## Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with Kalydeco, Trikafta or Symdeko.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	1 year 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 mees A, B and C: A) pt has two copies of the F508del mutation in the CTFR 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.
<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
<b>Exclusion Criteria</b>	N/A
<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>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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

## Products Affected

- OXERVATE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Treatment duration greater than 16 weeks per affected eye(s)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by an ophthalmologist or an optometrist
<b>Coverage Duration</b>	Initial-8 weeks, continuation-approve for an additional 8 weeks
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## PADCEV

### Products Affected

- PADCEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<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. 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PANRETIN

## Products Affected

- PANRETIN

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

# PAVBLU

## 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

## Products Affected

- PEMAZYRE

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

# PENICILLAMINE

## Products Affected

- *penicillamine oral tablet*

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

# PHENYL BUTYRATE

## Products Affected

- 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

- *metyrosine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior medication trials
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial and continuation therapy for metyrosine)
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin). If the requested drug is metyrosine for continuation therapy, approve if the patient is currently receiving metyrosine or has received metyrosine in the past.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## PHOSPHATE BINDERS AND SIMILAR AGENTS

### Products Affected

- calcium acetate(phosphat bind)
- sevelamer carbonate oral tablet

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

- *alyq*
- *sildenafil (pulmonary arterial hypertension) oral tablet 20 mg*
- *tadalafil (pulmonary arterial hypertension) oral tablet 20 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use With Guanylate Cyclase Stimulators.
<b>Required Medical Information</b>	Diagnosis, right heart cath results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PIRFENIDONE

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	1 year
Other Criteria	IPF (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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# POLIVY

## Products Affected

- POLIVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	B-Cell Lymphoma
<b>Part B Prerequisite</b>	No

# POMALYST

## Products Affected

- POMALYST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Kaposi Sarcoma/MM-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma
<b>Part B Prerequisite</b>	No

## POSACONAZOLE (ORAL)

### Products Affected

- *posaconazole oral tablet, delayed release (dr/ec)*

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

# POTELIGEO

## Products Affected

- POTELIGEO

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

# PREVYMIS

## Products Affected

- PREVYMIS INTRAVENOUS
- 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

## Products Affected

- CONEXXENCE
- JUBBONTI
- PROLIA

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

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

# PROMACTA

## Products Affected

- *eltrombopag olamine*
- PROMACTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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)
<b>Coverage Duration</b>	ImmuneThrombo/MDS init3mo,cont1yr,AAinit4mo,cont1yr,Thrombo/HepC1yr,Transplant-init3mo,cont6mo
<b>Other Criteria</b>	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

PA Criteria	Criteria Details
	<p>Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk 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.</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

# PYRIMETHAMINE

## Products Affected

- *pyrimethamine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Patient's immune status (Toxoplasma gondii Encephalitis, chronic maintenance and prophylaxis, primary)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis
<b>Part B Prerequisite</b>	No

# QINLOCK

## Products Affected

- QINLOCK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other therapies tried
<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>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Melanoma, cutaneous
<b>Part B Prerequisite</b>	No

# RADICAVA ORS

## Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT SUSP

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	ALSFRS-R score
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS (initial and continuation).
<b>Coverage Duration</b>	Initial, 6 months. Continuation, 6 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RECLAST

## Products Affected

- *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-

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

## REMODULIN

### Products Affected

- *treprostinil sodium*

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

PA Criteria	Criteria Details
	test, OR d) Patient cannot take CCB therapy, OR e) Patient has tried one CCB. Continuation-Approve if the patient meets ALL of the following conditions (a and b): a) Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH), AND b) Patient meets the following criteria [(1) and (2)]: (1) Patient has had a right heart catheterization, AND (2) Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# REPATHA

## Products Affected

- REPATHA
- REPATHA PUSHTRONEX
- REPATHA SURECLICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of Leqvio or Praluent.
<b>Required Medical Information</b>	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
<b>Age Restrictions</b>	ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Approve for 1 year
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RETEVMO

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors-2 years and older, all others 18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anaplastic thyroid carcinoma, histiocytic neoplasm

PA Criteria	Criteria Details
Part B Prerequisite	No

# REVUFORJ

## 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

# 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): 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</p>

PA Criteria	Criteria Details
	in combination with appropriate diet and exercise therapy (prescriber attestation the patient has received counseling on diet and exercise).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# REZLIDHIA

## Products Affected

- REZLIDHIA

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

# REZUROCK

## Products Affected

- REZUROCK

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

# RILUZOLE

## Products Affected

- *riluzole*

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

# RINVOQ

## Products Affected

- RINVOQ ORAL TABLET EXTENDED  
RELEASE 24 HR 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
<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

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

## ROFLUMILAST (ORAL)

### Products Affected

- *roflumilast*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
<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>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ROMVIMZA

## 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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	NSCLC-18 years and older, Solid Tumors-1 month and older, Pediatric Diffuse High-Grade Glioma-less than 18 years old
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pediatric Diffuse High-Grade Glioma
<b>Part B Prerequisite</b>	No

# RUBRACA

## Products Affected

- RUBRACA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma

PA Criteria	Criteria Details
Part B Prerequisite	No

# RUFINAMIDE

## Products Affected

- *rufinamide*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Patients 1 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial therapy-approve if rufinamide is being used for adjunctive treatment. Continuation-approve if the patient is responding to therapy
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Treatment-Refractory Seizures/Epilepsy
<b>Part B Prerequisite</b>	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

## Products Affected

- RYBREVANT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	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 pt has locally advanced or metastatic disease AND either (A or B): (A) the 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RYDAPT

## Products Affected

- RYDAPT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For AML, FLT3 status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myeloid or lymphoid Neoplasms with eosinophilia
<b>Part B Prerequisite</b>	No

# RYTELO

## Products Affected

- RYTELO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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 hematologist or oncologist (initial)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. INITIAL THERAPY: MYELODYSPLASTIC 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.
<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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous treatments/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Enterocutaneous fistula/diarrhea chemo - 3 months, small bowel bleed - 6 mos, all others - 1 year
<b>Other Criteria</b>	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/

PA Criteria	Criteria Details
	angiodysplasia related bleeding: pt has chronic, recurrent gastrointestinal bleeds lasting greater than or equal to 3 months.
<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

# SAPROPTERIN

## Products Affected

- *sapropterin*

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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SCSEMBLIX

## Products Affected

- SCSEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myeloid/Lymphoid Neoplasms with Eosinophilia
<b>Part B Prerequisite</b>	No

# SIGNIFOR

## Products Affected

- SIGNIFOR

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 (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy)
<b>Coverage Duration</b>	Cushing's disease/syndrome-Initial therapy - 4 months, Continuation therapy - 1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SIRTURO

## Products Affected

- SIRTURO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients weighing less than 8 kg
<b>Required Medical Information</b>	Diagnosis, concomitant therapy
<b>Age Restrictions</b>	Patients 2 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with an infectious diseases specialist or pulmonologist
<b>Coverage Duration</b>	9 months
<b>Other Criteria</b>	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
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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
<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/UC-18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	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)
<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 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

## SKYRIZI IV

### Products Affected

- SKYRIZI INTRAVENOUS

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>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	Approve for 3 doses
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## SOFOSBUVIR/VELPATASVIR

### Products Affected

- SOFOSBUVIR-VELPATASVIR

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>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied according to AASLD 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

# SOMAVERT

## Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	1 year
Other Criteria	ACROMEGALY (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

- *sorafenib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Bone cancer, approve if the patient has recurrent chordoma or has osteosarcoma and has tried one standard chemotherapy regimen. GIST, approve if the patient has tried TWO of the following: imatinib mesylate, avapritinib, sunitinib, dasatinib, ripretinib or regorafenib. Differentiated (ie, papillary, follicular, 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. Please note

<b>PA Criteria</b>	<b>Criteria Details</b>
	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

# SPRAVATO

## Products Affected

- SPRAVATO NASAL SPRAY, NON-AEROSOL 56 MG (28 MG X 2), 84 MG (28 MG X 3)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by a psychiatrist
<b>Coverage Duration</b>	MDD w/Acute Suicidal Ideation or Behavior - 2 months, Treatment-Resistant Depression - 6 months
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	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
- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	GIST/bone cancer/ melanoma, cutaneous-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	GIST, bone cancer, melanoma cutaneous
<b>Part B Prerequisite</b>	No

# STELARA

## Products Affected

- 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
- 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). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY for USTEKINUMAB SC: PLAQUE PSORIASIS (PP) [A or B]: A) tried one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, psoralen plus PUVA) for at least 3 months, unless intolerant or B) contraindication to MTX. (Note: a 3-month trial or intolerance of at least one biologic that is not Stelara or a Stelara biosimilar also counts.) CROHN'S DISEASE (CD): approve if pt receiving/received single IV loading dose within 2 months of initiating therapy with ustekinumab SC. ULCERATIVE COLITIS (UC): receiving/received single IV loading dose within 2 months of initiating therapy with ustekinumab SC. CONTINUATION THERAPY: PP/PsA/CD/UC: patient has responded to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

## STELARA IV

### Products Affected

- SELARSDI INTRAVENOUS
- STELARA 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

# STIVARGA

## Products Affected

- STIVARGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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):

<b>PA Criteria</b>	<b>Criteria Details</b>
	A) pt has recurrent, advanced, inoperable, or metastatic disease, and B) tried at least one systemic regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<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

# SUCRAID

## Products Affected

- SUCRAID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test 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 geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

# SUNITINIB

## Products Affected

- *sunitinib malate*

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>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<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.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<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

PA Criteria	Criteria Details
	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

## 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 mees 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

# TABRECTA

## Products Affected

- TABRECTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<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>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-small cell lung cancer with high-level MET amplification.
<b>Part B Prerequisite</b>	No

# TADALAFIL

## Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Indication for which tadalafil is being prescribed.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 mos.
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Tafinlar is being used. BRAF V600 mutations
<b>Age Restrictions</b>	1 year and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	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

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 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

# TAGRISSEO

## Products Affected

- TAGRISSEO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	<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>
<b>Indications</b>	All FDA-approved Indications.

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

# TALVEY

## Products Affected

- TALVEY

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

# TALZENNA

## Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Recurrent or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive disease. Prostate cancer - approve if the patient has metastatic castration resistant prostate cancer, AND is using this medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy AND the patient has homologous recombination repair (HRR) gene-mutated disease [Note: HRR gene mutations include ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C] AND the medication is used in combination with Xtandi (enzalutamide capsules and tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# 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

PA Criteria	Criteria Details
	synovitis/tenosynovial giant cell tumor, Myeloid/Lymphoid neoplasms with Eosinophilia, melanoma cutaneous.
<b>Part B Prerequisite</b>	No

# TAZAROTENE

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## Products Affected

- *tazarotene topical cream*
- *tazarotene topical gel*

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

# TAZVERIK

## Products Affected

- TAZVERIK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TECVAYLI

## Products Affected

- TECVAYLI

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

# TEPMETKO

## Products Affected

- TEPMETKO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-small cell lung cancer with high-level MET amplification.
<b>Part B Prerequisite</b>	No

# TERIPARATIDE

## Products Affected

- BONSITY
- *teriparatide (only ndcs starting with 47781)*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/lifetime.
<b>Other Criteria</b>	<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.</p> <p>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

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>	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.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.
<b>Part B Prerequisite</b>	No

# TEVIMBRA

## Products Affected

- TEVIMBRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

PA Criteria	Criteria Details
	<p>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 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 esophageal 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

# 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, dapson, 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).

PA Criteria	Criteria Details
	Histiocytic neoplasms-approve if pt has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman cutaneous disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, IDH1 Status
<b>Age Restrictions</b>	All diagnoses (except chondrosarcoma)-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chondrosarcoma, Central nervous system cancer
<b>Part B Prerequisite</b>	Yes

# TIVDAK

## Products Affected

- TIVDAK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<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. 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Vaginal cancer
<b>Part B Prerequisite</b>	No

## TOBRAMYCIN (NEBULIZATION)

### Products Affected

- tobramycin in 0.225 % nacl
- tobramycin inhalation

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

# TOLVAPTAN

## Products Affected

- *tolvaptan*

PA Criteria	Criteria Details
<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

### Products Affected

- *pimecrolimus*
- *tacrolimus topical*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

## TOPICAL RETINOID PRODUCTS

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### Products Affected

- *tretinoin topical*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coverage is not provided for cosmetic use.
<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 12 months
<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

## TOPIRAMATE/ZONISAMIDE

### Products Affected

- EPRONTIA
- *topiramate oral capsule, sprinkle 15 mg, 25 mg*
- *topiramate oral solution*
- *topiramate oral tablet*
- 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 transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute (i.e., non-chronic) pain.
<b>Required Medical Information</b>	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.

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

## TRANSMUCOSAL FENTANYL DRUGS

### Products Affected

- *fentanyl citrate buccal lozenge on a handle 200 mcg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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 12 months.
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TRELSTAR

## Products Affected

- TRELSTAR INTRAMUSCULAR  
SUSPENSION FOR RECONSTITUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	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.
<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. 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Head and neck cancer - salivary gland tumors
<b>Part B Prerequisite</b>	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

## Products Affected

- TREMFYA INTRAVENOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic oral small molecule drug.
<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>	3 doses for induction
<b>Other Criteria</b>	ULCERATIVE COLITIS-Approve if the medication will be used as induction therapy. CROHN'S DISEASE (CD): Approve if the patient medication will be used as induction therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TRIENTINE

## Products Affected

- *trientine oral capsule 250 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.

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

# TRIKAFTA

## Products Affected

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

PA Criteria	Criteria Details
<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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TRUQAP

## Products Affected

- TRUQAP

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

PA Criteria	Criteria Details
Part B Prerequisite	No

# TUKYSA

## Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Breast Cancer-approve if the patient has recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Biliary tract cancer
<b>Part B Prerequisite</b>	No

# TURALIO

## Products Affected

- TURALIO ORAL CAPSULE 125 MG

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

## 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>	INITIAL THERAPY- RHEUMATOID ARTHRITIS (RA) [A OR B]: A) Try TWO of the following: Enbrel, a preferred adalimumab product, Rinvoq, Oencia 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, Oencia, 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.

PA Criteria	Criteria Details
	CONTINUATION THERAPY-RA, PJIA, SJIA, GCA: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

## UPTRAVI

### Products Affected

- 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 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

# VALCHLOR

## Products Affected

- VALCHLOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Cutaneous lymphoma-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Adults with T-cell leukemia/lymphoma, Langerhans Cell Histiocytosis
<b>Part B Prerequisite</b>	No

# VALTOCO

## Products Affected

- VALTOCO

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

# VANCOMYCIN

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## Products Affected

- *vancomycin oral capsule 125 mg, 250 mg*

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

# VANFLYTA

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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

# 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.

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<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

# VERZENIO

## Products Affected

- VERZENIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Breast cancer: HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<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</p>

PA Criteria	Criteria Details
	<p>criteria (i, ii, or iii): i.Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.pt meets 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

- *vigabatin*
- *vigadrone*
- *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 mos. Treatment-Refractory Partial Seizures- initial- 3 mos, 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

# VIMIZIM

## Products Affected

- VIMIZIM

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

# VITRAKVI

## Products Affected

- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, NTRK gene fusion status
<b>Age Restrictions</b>	Pediatric Diffuse High-Grade Glioma- less than or equal to 21 years old
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pediatric Diffuse High-Grade Glioma
<b>Part B Prerequisite</b>	No

# VIZIMPRO

## Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, EGFR status, exon deletions or substitutions
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VONJO

## Products Affected

- VONJO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<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>	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 x 10 <sup>9</sup> /L (less than 50,000/mcL) OR (B) Patient has a platelet count of greater than or equal to 50 x 10 <sup>9</sup> /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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Accelerated or blast phase myeloproliferative neoplasm
<b>Part B Prerequisite</b>	No

# VORANIGO

## Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## VORICONAZOLE (ORAL)

### Products Affected

- *voriconazole*

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

# VOSEVI

## Products Affected

- VOSEVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 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.
<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

# VOTRIENT

## Products Affected

- *pazopanib oral tablet 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>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<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. 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>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<b>Off-Label Uses</b>	Differentiated (ie, papillary, follicular, oncocytic carcinoma) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or 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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VYLOY

## Products Affected

- VYLOY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<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. 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Esophageal adenocarcinoma
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>	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

PA Criteria	Criteria Details
	should be no more frequent than every 50 days from the start of the previous treatment cycle.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# WELIREG

## Products Affected

- WELIREG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Pheochromocytoma/paraganglioma-12 years and older, Other indications-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.

PA Criteria	Criteria Details
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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Anaplastic large cell lymphoma/IMT-patients greater than or equal to 1 year of age. All other diagnoses-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 Lorbrina 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.

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<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

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

# XERMELO

## Products Affected

- XERMELO

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

# XIAFLEX

## Products Affected

- XIAFLEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Retreatment for Peyronie's Disease (i.e., treatment beyond eight injections).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	Dupuytren's Contracture-3 months, Peyronie's Disease-6 months
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XIFAXAN

## Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Traveler's diarrhea - 12 years of age or older. Hepatic encephalopathy, irritable bowel syndrome with diarrhea - 18 years of age or older.
<b>Prescriber Restrictions</b>	Pouchitis - prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	Enceph-6 mo, IBS w/diarrhea-14 days, TD-3 days, intest bact overgrowth-14 days, Pouchitis - 1 year
<b>Other Criteria</b>	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.

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<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%

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

# XOSPATA

## Products Affected

- XOSPATA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, FLT3-mutation status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Lymphoid, Myeloid Neoplasms
<b>Part B Prerequisite</b>	No

# XPOVIO

## Products Affected

- XPOVIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Multiple Myeloma-Approve if the patient meets the following (A and B): A) The medication will be taken in combination with dexamethasone AND B) Patient meets one of the following (i, ii, or iii): i. Patient has tried at least four prior regimens for multiple myeloma OR ii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib OR iii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with Darzalex (daratumumab infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

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

# XTANDI

## Products Affected

- XTANDI ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Xtandi is being used.
<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>	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.]
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XYREM

## Products Affected

- SODIUM OXYBATE (PREFERRED NDCS STARTING WITH 00054)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with Xywav, Wakix or Sunosi
<b>Required Medical Information</b>	Medication history (as described in Other Criteria field)
<b>Age Restrictions</b>	7 years and older
<b>Prescriber Restrictions</b>	Prescribed by a sleep specialist physician or a Neurologist
<b>Coverage Duration</b>	12 months.
<b>Other Criteria</b>	For Excessive daytime sleepiness (EDS) in patients with narcolepsy, 18 years and older - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). For EDS in patients with narcolepsy, less than 18 years old-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextramphetamine) or modafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ZEJULA

## Products Affected

- ZEJULA ORAL TABLET

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>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Uterine Leiomyosarcoma, Ovarian, fallopian tube or primary peritoneal cancer-treatment
<b>Part B Prerequisite</b>	No

# ZELBORAF

## Products Affected

- ZELBORAF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	BRAFV600 mutation status required.
<b>Age Restrictions</b>	All diagnoses (except CNS cancer)-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	<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</p>

PA Criteria	Criteria Details
	OR ii. Pulmonary disease OR iii. Central nervous system lesions AND the patient has BRAF V600-mutation positive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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
<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

# ZIIHERA

## Products Affected

- ZIIHERA

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

# ZOLINZA

## Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

## ZTALMY

### Products Affected

- ZTALMY

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

## ZURZUVAE

### Products Affected

- ZURZUVAE 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

## 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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<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>	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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement. Erdheim-Chester disease. Peripheral T-Cell Lymphoma.
<b>Part B Prerequisite</b>	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

## Products Affected

- ZYNLONTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	HIV-related B-Cell Lymphoma, Post-transplant lymphoproliferative disorders
<b>Part B Prerequisite</b>	No

# ZYNYZ

## Products Affected

- ZYNYZ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anal carcinoma
<b>Part B Prerequisite</b>	No

## ZYTIGA

### Products Affected

- *abiraterone oral tablet 250 mg, 500 mg*
- *abirtega*

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	<p>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.</p>

PA Criteria	Criteria Details
	<p>Prostate cancer- radical prostatectomy or post radiation therapy-approve if 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

### Products Affected

- ABRAXANE
- *acetylcysteine*
- *acyclovir sodium intravenous solution*
- ADCETRIS
- *albuterol sulfate inhalation solution for nebulization*
- ALIQOPA
- *amiodarone intravenous solution*
- *amphotericin b*
- *aprepitant*
- *arformoterol*
- *arsenic trioxide*
- *azacitidine*
- *azathioprine oral tablet 50 mg*
- *azathioprine sodium*
- BAVENCIO
- BELEODAQ
- *bendamustine intravenous recon soln*
- BENDEKA
- BESPONSA
- *bleomycin*
- BLINCYTO INTRAVENOUS KIT
- BOMYNTRA
- BORTEZOMIB INJECTION RECON SOLN 1 MG, 2.5 MG
- *bortezomib injection recon soln 3.5 mg*
- *budesonide inhalation suspension for nebulization 0.25 mg/2 ml, 0.5 mg/2 ml, 1 mg/2 ml*
- *busulfan*
- *carboplatin intravenous solution*
- *carmustine intravenous recon soln 100 mg*
- *cidofovir*
- *cisplatin intravenous solution*
- *cladribine*
- CLINIMIX 5%/D15W SULFITE FREE
- CLINIMIX 4.25%/D10W SULF FREE
- CLINIMIX 4.25%/D5W SULFIT FREE
- CLINIMIX 5%-D20W(SULFITE-FREE)
- CLINIMIX 6%-D5W (SULFITE-FREE)
- CLINIMIX 8%-D10W(SULFITE-FREE)
- CLINIMIX 8%-D14W(SULFITE-FREE)
- *clofarabine*
- *cromolyn inhalation*
- *cyclophosphamide intravenous recon soln*
- *cyclophosphamide oral capsule*
- CYCLOPHOSPHAMIDE ORAL TABLET
- *cyclosporine modified*
- *cyclosporine oral capsule*
- CYRAMZA
- *cytarabine*
- *cytarabine (pf)*
- *dacarbazine*
- *dactinomycin*
- DANYELZA
- DARZALEX
- *daunorubicin*
- *decitabine*
- *deferoxamine*
- *dexrazoxane hcl*
- *dobutamine*
- *dobutamine in d5w intravenous parenteral solution 1,000 mg/250 ml (4,000 mcg/ml), 250 mg/250 ml (1 mg/ml), 500 mg/250 ml (2,000 mcg/ml)*
- *docetaxel*
- *dopamine in 5 % dextrose*
- *dopamine intravenous solution 200 mg/5 ml (40 mg/ml), 400 mg/10 ml (40 mg/ml)*
- *doxorubicin*
- *doxorubicin, peg-liposomal*
- *dronabinol*
- ELZONRIS
- EMLICITI
- ENGERIX-B (PF)
- ENGERIX-B PEDIATRIC (PF)
- ENVARSUS XR
- *epirubicin intravenous solution 200 mg/100 ml*
- ERBITUX
- *eribulin*

- ERWINASE
- ETOPOPHOS
- *etoposide intravenous*
- *everolimus (immunosuppressive)*
- *floxuridine*
- *fludarabine*
- *fluorouracil intravenous*
- *formoterol fumarate*
- *fulvestrant*
- *ganciclovir sodium*
- GAZYVA
- *gemcitabine intravenous recon soln*
- *gemcitabine intravenous solution 1 gram/26.3 ml (38 mg/ml), 2 gram/52.6 ml (38 mg/ml), 200 mg/5.26 ml (38 mg/ml)*
- GEMCITABINE INTRAVENOUS SOLUTION 100 MG/ML
- *gengraf*
- GRAFAPEX
- *granisetron hcl oral*
- HEPLISAV-B (PF)
- HIZENTRA
- *idarubicin*
- *ifosfamide*
- IMFINZI
- *intralipid intravenous emulsion 20 %*
- *ipratropium bromide inhalation*
- *ipratropium-albuterol*
- *irinotecan*
- ISTODAX
- IXEMPRA
- JEVTANA
- JYLAMVO
- JYNNEOS (PF)
- KHAPZORY INTRAVENOUS RECON SOLN 175 MG
- KIMMTRAK
- KYPROLIS
- *levoleucovorin calcium*
- *melphalan hcl*
- *mesna intravenous*
- *methotrexate sodium*
- *methotrexate sodium (pf)*
- *methylprednisolone oral tablet*
- *milrinone*
- *milrinone in 5 % dextrose*
- *mitomycin intravenous*
- *mitoxantrone*
- *mycophenolate mofetil*
- *mycophenolate mofetil (hcl)*
- *mycophenolate sodium*
- MYHIBBIN
- MYLOTARG
- *nelarabine*
- *nitroglycerin in 5 % dextrose intravenous solution 100 mg/250 ml (400 mcg/ml), 25 mg/250 ml (100 mcg/ml), 50 mg/250 ml (200 mcg/ml)*
- *nitroglycerin intravenous*
- NULOJIX
- ONCASPAR
- *ondansetron hcl oral solution*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet, disintegrating 4 mg, 8 mg*
- ONIVYDE
- *oxaliplatin*
- *paclitaxel*
- *paclitaxel protein-bound*
- *pemetrexed disodium intravenous recon soln*
- *pentamidine inhalation*
- PERJETA
- PLENAMINE
- *plerixafor*
- PRALATREXATE
- *premasol 10 %*
- PROGRAF INTRAVENOUS
- PROGRAF ORAL GRANULES IN PACKET
- PULMOZYME
- RECOMBIVAX HB (PF)
- *romidepsin intravenous recon soln*
- RYLAZE
- SIMULECT
- *sirolimus*
- *sodium nitroprusside*
- SYLVANT

- *tacrolimus oral capsule*
- TECENTRIQ
- TECENTRIQ HYBREZA
- TEMODAR INTRAVENOUS
- *temsirolimus*
- *thiotepa*
- TICE BCG
- *topotecan*
- *travasol 10 %*
- TRAZIMERA
- TROPHAMINE 10 %
- TYVASO
- TYVASO INSTITUTIONAL START KIT
- TYVASO REFILL KIT
- TYVASO STARTER KIT
- UNITUXIN
- *valrubicin*
- VARUBI
- VECTIBIX
- *veletri*
- *vinblastine*
- *vincristine*
- *vinorelbine*
- VYXEOS
- WYOST
- XGEVA
- YERVOY
- YONDELIS
- ZALTRAP
- ZANOSAR
- ZIRABEV
- *zoledronic acid intravenous solution*

### **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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