# 2024 Prior Authorization (PA) Criteria

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

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

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

Updated: 05/2024 Y0026_204249_C

# ACTEMRA

## Products Affected

- Actemra intravenous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use). |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy). |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | RA initial - approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, 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, infliximab, golimumab SC/IV, or a non-preferred adalimumab product will also count. A trial of multiple adalimumab products counts as ONE product). OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial-approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, Orencia, Xeljanz or a preferred adalimumab product. (Note: if the patient does not meet this requirement, a previous trial with the drug infliximab or a non-preferred adalimumab product will be counted towards meeting the try TWO requirement. A trial |

| PA Criteria | Criteria Details |
|---|---|
| | of multiple adalimumab products counts as ONE product.), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx, RA/PJIA - approve if the pt had a response as determined by the prescriber. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Hyrimoz (NDCs starting with -61314), adalimumab-adaz, adalimumab-adbm. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ACTEMRA SQ

## Products Affected

- Actemra ACTPen
- Actemra subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | Interstitial lung disease-18 years and older (initial and continuation) |
| **Prescriber Restrictions** | RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont) |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | RA initial - approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, 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, infliximab, golimumab SC/IV, or another non-preferred adalimumab product will also count. Trials of multiple adalimumab products count as ONE preferred. OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial-approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, Orencia, Xeljanz or a preferred adalimumab product. (Note: if the patient does not meet this requirement, a previous trial with the drug infliximab or a non-preferred adalimumab product will be counted towards meeting the try TWO requirement. Trials of multiple adalimumab products counts as ONE Preferred Product.), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx, RA/PJIA - approve if the pt had a |

| PA Criteria | Criteria Details |
|---|---|
| | response as determined by the prescriber. Interstitial lung disease associated with systemic sclerosis initial-approve if the patient has elevated acute phase reactants AND the diagnosis is confirmed by high-resolution computed tomography. Interstitial lung disease assoc with systemic sclerosis, Cont tx-approve if the patient had adequate efficacy. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Hyrimoz (NDCs starting with -61314), adalimumab-adaz, adalimumab-adbm. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ACYCLOVIR (TOPICAL)

## Products Affected

- acyclovir topical ointment

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

# ADALIMUMAB OTHER

## Products Affected

- adalimumab-adaz
- adalimumab-adbm subcutaneous pen injector kit
- adalimumab-adbm subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL
- adalimumab-adbm(CF) pen Crohns
- adalimumab-adbm(CF) pen PS-UV
- Cyltezo(CF) Pen
- Cyltezo(CF) Pen Crohn's-UC-HS
- Cyltezo(CF) Pen Psoriasis-UV
- Cyltezo(CF) subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL
- Hyrimoz Pen Crohn's-UC Starter (Preferred NDCs starting with 61314)
- Hyrimoz Pen Psoriasis Starter (Preferred NDCs starting with 61314)
- Hyrimoz(CF) (Preferred NDCs starting with 61314) subcutaneous syringe 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL
- Hyrimoz(CF) Pedi Crohn Starter (Preferred NDCs starting with 61314) subcutaneous syringe 80 mg/0.8 mL, 80 mg/0.8 mL- 40 mg/0.4 mL
- Hyrimoz(CF) Pen (Preferred NDCs starting with 61314)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another biologic DMARD or targeted synthetic DMARD. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous therapies tried |
| **Age Restrictions** | CD, 6 or older (initial). UC, 5 or older (initial). PP-18 years and older (initial) |
| **Prescriber Restrictions** | Init tx only-RA/JIA/JRA/Ankylosing spondylitis, prescr/consult w/rheum. PsA, prescr/consult w/rheum or derm. PP, prescr/consult w/derm. UC/ CD, prescr/consult w/gastro. HS, presc/consult w/derm. UV, prescr/consult w/ophthalmologist. |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional |

| PA Criteria | Criteria Details |
|---|---|
| | synthetic DMARD). JIA/JRA initial. Tried one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. Plaque psoriasis (PP) initial. approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). cont tx - must respond to tx as determined by prescriber. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ADBRY

## Products Affected

- Adbry

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another monoclonal antibody therapy (i.e., Dupixent, Cinqair, Fasenra, Nucala, Tazespire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical]. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | AD-12 years of age and older (initial therapy) |
| **Prescriber Restrictions** | Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy) |
| **Coverage Duration** | Initial-Atopic Dermatitis-4 months, Continuation-1 year |
| **Other Criteria** | Atopic Dermatitis, initial-patient has atopic dermatitis involvement estimated to be greater than or equal to 10 percent of the body surface area and patient meets a and b: a. Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid AND b. Inadequate efficacy was demonstrated with the previously tried topical corticosteroid therapy.Continuation- Approve if the patient has been receiving Adbry for at least 4 months and patient has responded to therapy. Note:  A patient who has received less than 4 months of therapy or who is restarting therapy with Adbry should be considered under initial therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ADEMPAS

## Products Affected

- Adempas

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ADSTILADRIN

## Products Affected

- Adstiladrin

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

# AIMOVIG

## Products Affected

- Aimovig Autoinjector

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination therapy with Ajovy, Vyepti or Emgality |
| **Required Medical Information** | Diagnosis, number of migraine headaches per month, prior therapies tried |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least one standard prophylactic pharmacologic therapy (e.g., anticonvulsant, beta-blocker), and has had inadequate response or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try a standard prophylactic pharmacologic therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AKEEGA

## Products Affected

- Akeega

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

# ALDURAZYME

## Products Affected

- Aldurazyme

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

# ALECENSA

## Products Affected

- Alecensa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Non-small cell lung cancer-approve if the patient has advanced or metastatic disease and anaplastic lymphoma kinase (ALK)-positive disease as detected by an approved test. Anaplastic large cell lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease and (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor- pt has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) pt has advanced, recurrent or metastatic disease, or (ii) tumor is inoperable. Large B-Cell Lymphoma- pt has ALK-positive disease AND pt has relapsed or refractory disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# ALOSETRON

## Products Affected

- alosetron

| 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

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

# ALUNBRIG

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | ALK status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has ALK positive disease and has advanced, recurrent or metastatic disease or the tumor is inoperable. NSCLC, must be ALK-positive, as detected by an approved test, have advanced or metastatic disease and patients new to therapy must have a trial of Alecensa prior to approval of Alunbrig. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT) |
| **Part B Prerequisite** | No |

# ANTIBIOTICS (IV)

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **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 |

# ANTIFUNGALS (IV)

## Products Affected

- fluconazole in NaCl (iso-osm)
- voriconazole

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

# APOKYN

## Products Affected

- APOKYN
- apomorphine

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

# ARCALYST

## Products Affected

- Arcalyst

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent biologic therapy |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age. |
| **Prescriber Restrictions** | Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA initial-rheum, geneticist, derm, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum |
| **Coverage Duration** | CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont |
| **Other Criteria** | CAPS renewal - approve if the patient has had a response as determined by the prescriber. DIRA initial-approve if the patient weighs at least 10 kg, genetic test confirms a mutation in the IL1RN gene and the patient has demonstrated a clinical benefit with anakinra subcutaneous injection. DIRA cont-approve if the patient has responded to therapy. Pericarditis initial-approve if the patient has recurrent pericarditis AND for the current episode, the patient is receiving standard treatment or standard treatment is contraindicated. Continuation-approve if the patient has had a clinical response. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ARIKAYCE

## Products Affected

- Arikayce

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, previous medication history (as described in Other Criteria field) |
| **Age Restrictions** | MAC-18 years and older (initial therapy) |
| **Prescriber Restrictions** | MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections. Cystic fibrosis-prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis |
| **Coverage Duration** | 1 year |
| **Other Criteria** | MAC Lung disease, initial-approve if the patient has a positive sputum culture for mycobacterium avium complex and the culture was collected within the past 3 months and was collected after the patient has completed a background multidrug regimen, the Mycobacterium avium complex isolate is susceptible to amikacin according to the laboratory report AND Arikayce will be used in conjunction to a background multidrug regimen. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin). MAC Lung Disease, continuation-approve if Arikayce will be used in conjunction with a background multidrug regimen AND i. Patient meets ONE of the following criteria (a or b):a)patient has not achieved negative sputum cultures for Mycobacterium avium complex OR b) patient has achieved negative sputum cultures for Mycobacterium avium complex for less than 12 months. Cystic fibrosis-patient has pseudomonas aeruginosa in culture of the airway. |

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

# ASPARLAS

## Products Affected

- Asparlas

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

# AUBAGIO

## Products Affected

- teriflunomide

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

# AUGTYRO

## Products Affected

- Augtyro

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Non-Small Cell Lung Cancer-approve if the patient has locally advanced or metastatic disease, patient has ROS1-positive non-small cell lung cancer and the mutation was detected by an approved test. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AVONEX

## Products Affected

- Avonex intramuscular pen injector kit
- Avonex intramuscular syringe kit

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

# AYVAKIT

## Products Affected

- Ayvakit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation or if the patient has tried two of the following: Gleevec (imatinib), Sutent (sunitinib), Sprycel (dasatinib), Stivarga (regorafenib) or Qinlock (ripretinib). Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for PDGFRA D842V mutation. Systemic mastocytosis-Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has either indolent systemic mastocytosis or one of the following subtypes of advanced systemic mastocytosis-aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm or mast cell leukemia. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Myeloid/Lymphoid neoplasms with Eosinophilia |
| **Part B Prerequisite** | No |

# BALVERSA

## Products Affected

- Balversa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, previous therapies, test results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy or checkpoint inhibitor therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BENLYSTA

## Products Affected

- Benlysta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with Other Biologics or Lupkynis |
| **Required Medical Information** | Diagnosis, medications that will be used in combination, autoantibody status |
| **Age Restrictions** | 18 years and older (initial). |
| **Prescriber Restrictions** | SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont) |
| **Coverage Duration** | SLE-Initial-4 months, cont-1 year. Lupus Nephritis-6 mo initial, 1 year cont |
| **Other Criteria** | Lupus Nephritis Initial-approve if the patient has a diagnosis of lupus nephritis confirmed on biopsy (For example, World Health Organization class III, IV, or V lupus nephritis), AND the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid). Cont-approve if the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid) AND the patient has responded to the requested medication. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA] AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician. |

| PA Criteria | Criteria Details |
|---|---|
| | Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician AND The patient has responded to Benlysta as determined by the prescriber. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BESREMI

## Products Affected

- Besremi

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

# BETASERON/EXTAVIA

## Products Affected

- Betaseron subcutaneous kit

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

# BEXAROTENE (ORAL)

## Products Affected

- bexarotene

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation) |
| **Coverage Duration** | 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 |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Adult T-Cell Leukemia/Lymphoma- approve if the patient has chronic/smoldering subtype and this medication is used as first-line therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Adult T-Cell Leukemia/Lymphoma |
| **Part B Prerequisite** | No |

# BONIVA INJECTION

## Products Affected

- ibandronate intravenous

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

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

# BOSENTAN/AMBRISENTAN

## Products Affected

- ambrisentan
- bosentan

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

# BOSULIF

## Products Affected

- Bosulif oral capsule 100 mg, 50 mg
- Bosulif oral tablet 100 mg, 400 mg, 500 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. For CML/ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies tried |
| **Age Restrictions** | CML- 1 year and older. ALL, myeloid/lymphoid neoplasms w eosinophilia-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | For Ph-positive CML, patients new to therapy must have tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel. For Ph-positive ALL, patients new to therapy must have tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia, myeloid/lymphoid neoplasms with eosinophilia |
| **Part B Prerequisite** | No |

# BRAFTOVI

## Products Affected

- Braftovi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, BRAF V600 status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. Colon or Rectal cancer- approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer. NSCLC- approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BRIUMVI

## Products Affected

- Briumvi

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

# BRUKINSA

## Products Affected

- Brukinsa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Mantle Cell Lymphoma - approve if the patient has tried at least one systemic regimen or patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail). Chronic lymphocytic leukemia/small lymphocytic lymphoma-approve. Marginal zone lymphoma-approve if the patient has tried at least one systemic regimen. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma-approve. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# C1 ESTERASE INHIBITORS

## Products Affected

- Cinryze

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

# CABLIVI

## Products Affected

- Cablivi injection kit

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

# CABOMETYX

## Products Affected

- Cabometyx

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, histology, RET gene rearrangement status for NSCLC |
| **Age Restrictions** | Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried Lenvima or sorafenib. Endometrial carcinoma-approve if the patient has tried one systemic regimen. GIST-approve if the patient has tried two of the following-imatinib, Ayvakit, sunitinib, dasatinib, Stivarga or Qinlock. NSCLC-approve if the patient has RET rearrangement psotivie tumor. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Patients with Non-Small Cell Lung Cancer, Gastrointestinal stromal tumors (GIST), Bone cancer, Endometrial Carcinoma |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# CALQUENCE

## Products Affected

- Calquence
- Calquence (acalabrutinib mal)

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

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# CAPRELSA

## Products Affected

- Caprelsa oral tablet 100 mg, 300 mg

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

# CARGLUMIC ACID

## Products Affected

- carglumic acid

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

# CAYSTON

## Products Affected

- Cayston

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

# CEPROTIN

## Products Affected

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

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

# CHEMET

## Products Affected

- Chemet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Blood lead level |
| **Age Restrictions** | Approve in patients between the age of 12 months and 18 years |
| **Prescriber Restrictions** | Prescribed by or in consultation with a professional experienced in the use of chelation therapy (eg, a medical toxicologist or a poison control center specialist) |
| **Coverage Duration** | Approve for 2 months |
| **Other Criteria** | Approve if Chemet is being used to treat acute lead poisoning (not as prophylaxis) and prior to starting Chemet therapy the patient's blood lead level was greater than 45 mcg/dL. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CHENODAL

## Products Affected

- Chenodal

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

# CHOLBAM

## Products Affected

- Cholbam oral capsule 250 mg, 50 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination Therapy with Chenodal |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with hepatologist, metabolic specialist, or GI |
| **Coverage Duration** | 3 mos initial, 12 mos cont |
| **Other Criteria** | Bile acid synthesis d/o due to SEDs initial - Diagnosis based on an abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis or molecular genetic testing consistent with the diagnosis. Cont - responded to initial Cholbam tx with an improvement in LFTs AND does not have complete biliary obstruction. Bile-Acid Synthesis Disorders Due to Peroxisomal Disorders (PDs), Including Zellweger Spectrum Disorders initial - PD with an abnormal urinary bile acid analysis by FAB-MS or molecular genetic testing consistent with the diagnosis AND has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g., rickets). Cont - responded to initial Cholbam therapy as per the prescribing physician (e.g., improvements in liver enzymes, improvement in steatorrhea) AND does not have complete biliary obstruction. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# CIBINQO

## Products Affected

- Cibinqo

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

| PA Criteria | Criteria Details |
|---|---|
| | patient experienced an improvement in at least one symptom, such as decreased itching. Note: A patient who has received less than 3 months of therapy or who is restarting therapy with Cibinqo should be considered under initial therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CIMERLI

## Products Affected

- Cimerli

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

# CIMZIA

## Products Affected

- Cimzia
- Cimzia Powder for Reconst
- Cimzia Starter Kit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD |
| **Required Medical Information** | Diagnosis, concurrent medications, previous therapies tried |
| **Age Restrictions** | 18 years and older for CD and PP (initial therapy). |
| **Prescriber Restrictions** | All dx initial therapy only. RA/AS, prescribed by or in consultation with a rheumatologist. Crohn's disease, prescribed by or in consultation with a gastroenterologist.PsA prescribed by or in consultation with a rheumatologist or dermatologist. PP, prescribed by or in consultation with a dermatologist. nr-axSpA-prescribed by or in consultation with a rheumatologist |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | AS initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Xeljanz/XR, Taltz. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. A trial of multiple adalimumab products counts as ONE preferred product. PsA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Taltz, Stelara, Otezla, Orencia, Rinvoq, Skyrizi or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. A trial of multiple adalimumab products counts as ONE preferred product. RA initial tx, approve if the patient has tried two of the following drugs in the past: Enbrel, a preferred adalimumab product, Orencia, Rinvoq or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product |

| PA Criteria | Criteria Details |
|---|---|
| | will also count. A trial of multiple adalimumab products counts as ONE preferred product. CD initial tx, approve if patient has previously tried a preferred adalimumab product. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. Plaque Psoriasis (PP), initial tx-approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Skyrizi, Stelara SC, Otezla, or Taltz. A trial of multiple preferred adalimumab products counts as ONE preferred product. Cont tx, AS/PsA/RA/CD/PP - approve if the pt had a response as determined by the prescriber. Non-radiographic axial spondylitis (nr-axSpA), initial tx-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroilitis reported on MRI. nr-axSpA continuation tx-approve if the patient has had a response as determined by the prescriber. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Hyrimoz (NDCs starting with -61314), adalimumab-adaz, adalimumab-adbm. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CINACALCET

## Products Affected

- cinacalcet

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

# CLOBAZAM

## Products Affected

- clobazam oral suspension
- clobazam oral tablet
- Sympazan

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

# CLOMIPHENE

## Products Affected

- Clomid
- clomiphene citrate

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

# COLUMVI

## Products Affected

- Columvi

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

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

# COMETRIQ

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 3 years. |
| **Other Criteria** | MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy and patient has tried a Vascular Endothelial Growth Factor Receptor (VEGFR)-targeted therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma |
| **Part B Prerequisite** | No |

# COPIKTRA

## Products Affected

- Copiktra

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma - approve if the patient has tried one systemic regimen (e.g., Imbruvica (ibrutinib capsules, tablets and oral solution), Venclexta (venetoclax tablets), rituximab, Gazyva (obinutuzumab intravenous infusion), chlorambucil, fludarabine, cyclophosphamide, bendamustine, high-dose methylprednisolone, Campath (alemtuzumab intravenous infusion), Calquence (acalabrutinib capsules), Brukinsa (zanubrutinib capsules), or Arzerra (ofatumumab intravenous infusion). T-cell lymphoma- For peripheral T-cell lymphoma, approve. For breast implant-associated anaplastic large cell lymphoma, or hepatosplenic T-cell lymphoma, approve if the patient has relapsed or refractory disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | T-cell Lymphoma |
| **Part B Prerequisite** | No |

# COTELLIC

## Products Affected

- Cotellic

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma initial - must have BRAF V600 mutation. |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf. CNS Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma OR b) isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma OR iii. Melanoma with brain metastases AND medication with be taken in combination with Zelboraf (vemurafenib tablets). Histiocytic Neoplasm-approve if the patient meets one of the following (i, ii, or iii): i. Patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease AND C) Patient has BRAF V600 mutation-positive disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | Central Nervous System Cancer |
| **Part B Prerequisite** | No |

# CRESEMBA (ORAL)

## Products Affected

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

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

# CYSTEAMINE (OPHTHALMIC)

## Products Affected

- Cystaran

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

# CYSTEAMINE (ORAL)

## Products Affected

- Cystagon

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

# DALFAMPRIDINE

## Products Affected

- dalfampridine

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

# DANYELZA

## Products Affected

- Danyelza

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

# DAURISMO

## Products Affected

- Daurismo oral tablet 100 mg, 25 mg

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

# DEFERASIROX

## Products Affected

- deferasirox

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

# DEFERIPRONE

## Products Affected

- deferiprone

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

# DIACOMIT

## Products Affected

- Diacomit

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

# DIMETHYL FUMARATE

## Products Affected

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

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

# DOPTELET

## Products Affected

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

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

# DROXIDOPA

## Products Affected

- droxidopa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Medication history (as described in Other Criteria field) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | NOH, approve if the patient meets ALL of the following criteria: a) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND b) Patient has tried midodrine |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DUPIXENT

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody (i.e., Adbry, Cinqair, Fasenra, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical]. |
| **Required Medical Information** | Diagnosis, prescriber specialty, other medications tried and length of trials |
| **Age Restrictions** | AD-6 months and older, asthma-6 years of age and older, Esophagitis-1 yr and older, Chronic Rhinosinusitis/Prurigo nodularis-18 and older |
| **Prescriber Restrictions** | Atopic Dermatitis/prurigo nodularis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Esophagitis-presc/consult-allergist or gastro |
| **Coverage Duration** | AD-Init-4mo, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/prurigo nod-init-6 mo, cont 1 yr |
| **Other Criteria** | AD, Init-pt 2yrs and older-pt meets a and b:a.used at least 1 med, med-high, high, and/or super-high-potency rx top corticosteroid OR has AD affecting ONLY face,eyes/eyelids,skin folds,and/or genitalia and has tried tacrolimus oint AND b.Inadeq efficacy demonstrated w/prev tx. AD, Init-pt between age of 6 mo and less than 2 yr-pt meets both a and b:a.has used at least 1 med, med-high, high, and/or super-high-potency rx top corticosteroid and b.inadeq efficacy demonstrated w/prev tx OR pt has AD affecting ONLY face,eyes/eyelids,skin folds,and/or genitalia.Cont-pt responded to Dupixent. Asthma,init-pt meets following (i, ii, and iii):i.Pt meets 1 of following(a or b):a)blood eosinophil level greater than or equal |

| PA Criteria | Criteria Details |
|---|---|
| | to 150 cells per microliter w/in prev 6 wks or within 6 wks prior to tx with any IL tx or Xolair OR b)has oral CS-dependent asthma, AND ii. received combo tx w/BOTH of the following (a and b): a)ICS AND b) 1 add asthma controller/maintenance med(NOTE:exception to the requirement for a trial of 1 add asthma controller/maint med can be made if pt already received anti-IL-5 tx or Xolair used concomitantly w/an ICS AND iii.asthma uncontrolled or was uncontrolled prior to starting anti-IL tx or Xolair defined by 1 (a, b, c, d or e): a)exper 2 or more asthma exacer req tx with systemic corticosteroids in previous yr OR b)exper 1 or more asthma exacer requiring hosp or ED/urgent care visit in prev yr OR c)FEV1 less than 80 percent predicted OR d)FEV1/FVC less than 0.80 OR e)asthma worsens w/tapering of oral CS tx.Cont-pt meets (i and ii): i.cont to receive tx with 1 ICS or 1 ICS-containing combo inhaler AND ii.has responded to Dupixent.Chronic rhinosinusitis with nasal polyposis,initial-pt receiving tx with an intranasal CS and experi rhinosinusitis symptoms like nasal obstruction, rhinorrhea, or reduction/loss of smell AND meets 1 of following (a or b): a)received tx w/syst CS w/in prev 2 yrs or has contraindication to systemic CS tx OR b)prior surgery for nasal polyps. Cont-pt cont to receive tx with an intranasal CS and responded to Dupixent. Eosinophilic esophagitis, initial- weighs greater than or equal to 15 kg, has dx of eosinophilic esophagitis confirmed by an endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, and does not have a secondary cause of eosinophilic esophagitis, and has received at least 8 wks of tx with a Rx strength PPI. Cont-pt has received at least 6 mo of tx with Dupixent and has experienced reduced intraepithelial eosinophil count or decreased dysphagia/pain upon swallowing or reduced frequency/severity of food impaction. Prurigo Nodularis, initial-pt has greater than or equal to 20 nodular lesions and pt has experienced pruritus at least 6 wks, AND tried at least 1 high- or super-high-potency Rx topical CS. Cont-pt has received at least 6 mo of tx with Dupixent and has experienced reduced nodular lesion count, decreased pruritis or reduced nodular lesion size. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ELAPRASE

## Products Affected

- Elaprase

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

# ELREXFIO

## Products Affected

- Elrexfio

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

# ELZONRIS

## Products Affected

- Elzonris

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

# EMGALITY

## Products Affected

- Emgality Pen
- EMGALITY SUBCUTANEOUS SYRINGE 120 MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination therapy with Aimovig, Vyepti or Ajovy |
| **Required Medical Information** | Diagnosis, number of migraine or cluster headaches per month, prior therapies tried |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Cluster headache tx-6 months, migraine prevention-1 year |
| **Other Criteria** | Migraine headache prevention-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least one standard prophylactic pharmacologic therapy (e.g., anticonvulsant, beta-blocker), and has had inadequate response or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try a standard prophylactic pharmacologic therapy. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# ENBREL

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with biologic therapy or targeted synthetic DMARD |
| **Required Medical Information** | Diagnosis, concurrent medications, previous therapies tried. |
| **Age Restrictions** | PP-4 years and older (initial therapy) |
| **Prescriber Restrictions** | Initial only-RA/AS/JIA/JRA,prescribed by or in consult w/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist.Plaque psoriasis (PP), prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center.Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist. |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other systemic therapy for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID), biologic or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide.Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) |

| PA Criteria | Criteria Details |
|---|---|
| | patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD-approve. Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Behcet's, GVHD-Cont-if the patient has had a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Graft versus host disease (GVHD), Behcet's disease |
| **Part B Prerequisite** | No |

# ENDARI

## Products Affected

- Endari

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

# ENTYVIO

## Products Affected

- Entyvio

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

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

# EPCLUSA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination use with other direct acting antivirals, excluding ribavirin. |
| **Required Medical Information** | Genotype (including unknown), prescriber specialty, other medications tried or used in combination with requested medication |
| **Age Restrictions** | 3 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| **Coverage Duration** | Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug |
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Indications consistent with current AASLD/IDSA guidance |
| **Part B Prerequisite** | No |

# EPIDIOLEX

## Products Affected

- Epidiolex

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

# EPKINLY

## Products Affected

- Epkinly

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-cell lymphoma - approve if the patient has received two or more lines of systemic therapy and the medication will be given as a single agent. Human immunodeficiency virus (HIV)-Related B-Cell Lymphoma - approve if the patient has received two or more lines of systemic therapy and the medication will be given as a single agent. Note:  HIV-related B-cell lymphomas includes HIV-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus-8 (HHV8) positive DLBCL. Post-transplant lymphoproliferative disorders - approve if the patient has received two or more lines of systemic therapy and the medication will be given as a single agent. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Human immunodeficiency virus (HIV)-Related B-Cell Lymphoma. Post-transplant lymphoproliferative disorders. |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# EPOETIN ALFA

## Products Affected

- Procrit
- Retacrit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | CRF anemia in patients not on dialysis.Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start.Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa, Mircera or Aranesp.Anemia w/myelosuppressive chemotx.pt must be currently receiving myelosuppressive chemo as a non-curative treatment, and Hb 10.0 g/dL or less to start.Hb less than or equal to 12.0 g/dL if previously on epoetin alfa or Aranesp.MDS, approve if Hb is 10 g/dL or less or serum erythropoietin level is  500 mU/mL or less to start.Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV with zidovudine, Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 mU/mL or less at tx start.Previously on EA approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Hgb is less than or equal to 13, surgery is elective, nonvascular and non-cardiac and pt is unwilling or unable to donate autologous blood prior to surgery |
| **Age Restrictions** | MDS anemia = 18 years of age and older |
| **Prescriber Restrictions** | MDS anemia, myelofibrosis- prescribed by or in consultation with, a hematologist or oncologist. |
| **Coverage Duration** | Chemo-6m,Transfus-1m, CKD-1yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr |
| **Other Criteria** | Myelofibrosis-Initial-patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 Mu/mL. Cont-approve if according to the prescriber the patient has had a response. Anemia in patients with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit). |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Anemia due to myelodysplastic syndrome (MDS), Myelofibrosis |
| **Part B Prerequisite** | No |

# ERIVEDGE

## Products Affected

- Erivedge

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | BCC (La or Met) - must not have had disease progression while on Odomzo. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Basal cell carcinoma, locally advanced-patients new to therapy-approve if the patient has tried Odomzo. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has medulloblastoma, the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway. Basal cell carcinoma, metastatic (this includes primary or recurrent nodal metastases and distant metastases)-approve. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Central nervous System Cancer |
| **Part B Prerequisite** | No |

# ERLEADA

## Products Affected

- Erleada oral tablet 240 mg, 60 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) agonist or the medication is concurrently used with Firmagon or if the patient has had a bilateral orchiectomy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ERLOTINIB

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Advanced or Metastatic NSCLC, approve if the patient has sensitizing EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of sensitizing EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. Advanced RCC, approve if the patient has recurrent or advanced non-clear cell histology RCC or if the patient had hereditary leiomyomatosis and renal cell carcinoma and erlotinib will be used in combination with bevacizumab. Bone cancer-approve if the patient has chordoma and has tried one previous therapy. Pancreatic cancer-approve if the medication is used in combination with gemcitabine and if the patient has locally advanced, metastatic or recurrent disease. Vulvar cancer-approve if the patient has advanced, recurrent or metastatic disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma. |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# EVEROLIMUS

## Products Affected

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

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

| PA Criteria | Criteria Details |
|---|---|
| | Carcinomas-approve if pt has tried chemotherapy or cannot tolerate chemotherapy.TSC associated renal angiomyolipoma -approve. WM/LPL -approve if pt has progressive or relapsed disease or if pt has not responded to primary therapy. Thyroid Carcinoma, differentiated-approve if pt is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if Afinitor will be used in combo with letrozole. GIST-approve if pt has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock or imatinib AND there is confirmation that Afinitor will be used in combo with 1 of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. TSC-associated partial-onset seizures-approve. NET tumors of the pancreas, GI Tract, Lung and Thymus (carcinoid tumors)-approve. Soft tissue sarcoma-approve if pt has perivascular epithloid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangioleiomyomatosis. Classic hodgkin lymphoma-approve if pt has relapsed or refractory disease. Histiocytic neoplasm-approve if pt has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis with bone disease, central nervous system lesions, multisystem disease or pulmonary disease. Patient must also have PIK3CA mutation. 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. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | neuroendocrine tumors of the thymus (Carcinoid tumors). Soft tissue sarcoma, classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST), men with breast cancer, Pre-peri-menopausal women with breast cancer, Histiocytic Neoplasm, uterine sarcoma |
| **Part B Prerequisite** | No |

# EXKIVITY

## Products Affected

- Exkivity

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC)-approve if the patient meets (A, B and C): A) Patient has locally advanced or metastatic NSCLC AND B) Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation, as determined by an approved test AND C) Patient has previously tried at least one platinum-based chemotherapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# EYLEA

## Products Affected

- Eylea

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

# FABRAZYME

## Products Affected

- Fabrazyme

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

# FASENRA

## Products Affected

- Fasenra
- Fasenra Pen

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another monoclonal antibody therapy. |
| **Required Medical Information** | Diagnosis, severity of disease, peripheral blood eosinophil count, previous therapies tried and current therapies, FEV1/FVC |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, or pulmonologist |
| **Coverage Duration** | Authorization will be for 6 months initial, 12 months continuation. |
| **Other Criteria** | Initial - must have peripheral blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with Fasenra or another monoclonal antibody therapy that may lower blood eosinophil levels AND meet both of the following criteria: 1) Patient has received combination therapy with an inhaled corticosteroid AND at least one additional asthma controller or asthma maintenance medication (Examples: LABA, LAMA, leukotrienes, monoclonal antibodies for asthma) AND 2) Patient's asthma is uncontrolled or was uncontrolled prior to receiving Fasenra or another monoclnal antibody therapy for asthma as defined by ONE of the following: a) patient experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, OR b) patient experienced one or more asthma exacerbation requiring hospitalization, an urgent care visit or an Emergency Department (ED) visit in the previous year, OR c) patient has a FEV1 less than 80 percent predicted, OR d) Patient has an FEV1/FVC less than 0.80, OR e) Patient's asthma worsens upon tapering of oral corticosteroid therapy. Continuation - The patient has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased |

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

# FINGOLIMOD

## Products Affected

- fingolimod

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use of fingolimod with other disease-modifying agents used for multiple sclerosis (MS). |
| **Required Medical Information** | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| **Age Restrictions** | 10 years and older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a neurologist or an MS specialist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FINTEPLA

## Products Affected

- Fintepla

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

# FIRDAPSE

## Products Affected

- Firdapse

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

# FIRMAGON

## Products Affected

- Firmagon kit w diluent syringe

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

# FOTIVDA

## Products Affected

- Fotivda

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. Note: Examples of systemic regimens for renal cell carcinoma include axitinib tablets, axitinib + pembrolizumab injection, cabozantinib tablets, cabozantinib + nivolumab injection, sunitinib malate capsules, pazopanib tablets, sorafenib tablets, and lenvatinib capsules + everolimus. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FRUZAQLA

## Products Affected

- Fruzaqla oral capsule 1 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Colon cancer, rectal cancer, or appendiceal cancer-Approve if the patient meets the following (A and B): A.Patient has advanced or metastatic disease, AND B.Patient has previously been treated with the following (i, ii, and iii): i.Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine. AND ii.An anti-vascular endothelial growth factor (VEGF) agent, Note: Examples of anti-VEGF agents include bevacizumab. AND iii. If the tumor is RAS wild-type (KRAS wild-type and NRAS wild-type) [that is, the tumor or metastases are KRAS and NRAS mutation negative], the patient meets ONE of the following (a or b): a.According to the prescriber, anti-epidermal growth factor receptor (EGFR) therapy is NOT medically appropriate, OR b. The patient has received an anti-EGFR therapy. Note: Examples of anti-EGFR therapy includes Erbitux (cetuximab intravenous infusion) and Vectibix (panitumumab intravenous infusion). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

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

# FYARRO

## Products Affected

- Fyarro

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

# GATTEX

## Products Affected

- Gattex 30-Vial
- Gattex One-Vial

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

# GAVRETO

## Products Affected

- Gavreto

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | NSCLC-18 years and older, thyroid cancer-12 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NSCLC-approve if the patient has metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion-positive disease or RET-mutation positive disease and has anaplastic thyroid cancer or the patient has medullary thyroid cancer or the disease is radioactive iodine-refractory. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Medullary Thyroid Cancer |
| **Part B Prerequisite** | No |

# GILOTRIF

## Products Affected

- Gilotrif

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For NSCLC - EGFR exon deletions or mutations, or if NSCLC is squamous cell type |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | NSCLC EGFR pos - For the treatment of advanced or metastatic non small cell lung cancer (NSCLC)-approve if the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: examples of sensitizing EGFR mutation-positive NSCLC include the following mutations : exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. NSCLC metastatic squamous cell must have disease progression after treatment with platinum based chemotherapy. Head and neck cancer-approve if the patient has non-nasopharyngeal head and neck cancer and the patient has disease progression on or after platinum based chemotherapy. (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan) |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Head and neck cancer |
| **Part B Prerequisite** | 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 |
|---|---|
| **Exclusion Criteria** | Concurrent use with other disease-modifying agent used for multiple sclerosis |
| **Required Medical Information** | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or after consultation with a neurologist or an MS specialist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GLUCAGON-LIKE PEPTIDE-1 AGONISTS

## Products Affected

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

| 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 |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Endometriosis-18 years and older |
| **Prescriber Restrictions** | Prostate cancer/Breast cancer/Head and Neck/Ovarian/Uterine-prescribed by or in consultation with an oncologist. Endometriosis/abnormal uterine bleeding-prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health. |
| **Coverage Duration** | Abnormal uterine bleeding-2 months, Endometriosis-6 months, all other dx-1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Abnormal uterine bleeding-Zoladex 3.6mg is used as an endometrial-thinning agent prior to endometrial ablation.Endometriosis-approve Zoladex 3.6 mg. Prostate cancer-approve Zoladex 3.6 mg and/or 10.8 mg. Head and Neck Cancer - Salivary Gland Tumors: approve if patient has recurrent, unresectable, or metastatic disease AND has androgen receptor-positive disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Zoladex 3.6mg only: head and neck cancer - salivary gland tumors, Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer, and Uterine Cancer |
| **Part B Prerequisite** | No |

# GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Premenstrual disorders - 18 years and older |
| **Prescriber Restrictions** | Prostate cancer-prescr/consult with oncologist or urologist. For the treatment of other cancer diagnosis must be prescribed by or in consultation with an oncologist. |
| **Coverage Duration** | uterine leiomyomata approve 3months/all other dx 12 mo |
| **Other Criteria** | Premenstrual disorders including PMS and PMDD- approve if pt has severe refractory premenstrual symptoms AND pt has tried an SSRI or combined oral contraceptive. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Ovarian cancer including fallopian tube and primary peritoneal cancer, breast cancer, prophylaxis or treatment of uterine bleeding or menstrual suppression in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors, premenstrual disorders including premenstrual syndrome and premenstrual dysphoric disorder, uterine cancer |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# GRALISE/HORIZANT/LYRICA CR

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GROWTH HORMONES

## Products Affected

- Omnitrope

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

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

| PA Criteria | Criteria Details |
|---|---|
| | Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | CKD, SHOX, SBS |
| **Part B Prerequisite** | No |

# HARVONI

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination use with other direct acting antivirals, excluding ribavirin |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 3 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD |
| **Coverage Duration** | Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug |
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Indications consistent with current AASLD/IDSA guidance |
| **Part B Prerequisite** | No |

# HETLIOZ

## Products Affected

- tasimelteon

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-24-patient is totally blind with no perception of light |
| **Age Restrictions** | Non-24-18 years or older (initial and continuation), SMS-3 years and older |
| **Prescriber Restrictions** | prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders (initial and continuation) |
| **Coverage Duration** | 6 mos initial, 12 mos cont |
| **Other Criteria** | Initial - patient is totally blind with no perception of light, dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy plus evaluation of sleep logs. Cont - Approve if patient is totally blind with no perception of light and pt has achieved adequate results with Hetlioz therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep). Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)-approve. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HIGH RISK MEDICATIONS - BENZODIAZEPINES

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Procedure-related sedation = 1mo. All other conditions = 12 months. |
| **Other Criteria** | All medically accepted indications other than insomnia, approve if the physician has assessed risk versus benefit in using the High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy. Insomnia, may approve lorazepam if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon and the physician has assessed risk versus benefit in using the HRM in this patient and has confirmed that he/she would still like initiate/continue therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# HIGH RISK MEDICATIONS - BENZTROPINE

## Products Affected

- benztropine oral

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | For all medically-accepted indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing benztropine for the patient and he/she would still like to initiate/continue therapy |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

## Products Affected

- cyclobenzaprine oral tablet 10 mg, 5 mg

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

# HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

## Products Affected

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

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

# HIGH RISK MEDICATIONS - PHENOBARBITAL

## Products Affected

- phenobarbital

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

# HIGH RISK MEDICATIONS- ESTROGENS

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Previous medication use |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 12 months |
| **Other Criteria** | For the treatment of Vulvar Vaginal Atrophy, approve if the patient has had a trial of one of the following for vulvar vaginal atrophy (brand or generic): Estradiol Vaginal Cream, Estring, Imvexxy, Premarin Vaginal Cream or estradiol valerate injection. For prophylaxis of Postmenopausal Osteoporosis, approve if the patient has had a trial of one of the following (brand or generic): alendronate, ibandronate, risedronate or Raloxifene. The physician has assessed risk versus benefit in using this High Risk medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy. |
| **Indications** | All Medically-accepted Indications. |

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

# HUMIRA

## Products Affected

- Humira (PREFERRED NDCS STARTING WITH 00074) subcutaneous syringe kit 40 mg/0.8 mL
- Humira Pen (PREFERRED NDCS STARTING WITH 00074)
- Humira Pen Psor-Uveits-Adol HS (PREFERRED NDCS STARTING WITH 00074)
- Humira(CF) (PREFERRED NDCS STARTING WITH 00074) subcutaneous syringe kit 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL
- Humira(CF) Pedi Crohns Starter (PREFERRED NDCS STARTING WITH 00074) subcutaneous syringe kit 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL
- Humira(CF) Pen (PREFERRED NDCS STARTING WITH 00074) subcutaneous pen injector kit 40 mg/0.4 mL, 80 mg/0.8 mL
- Humira(CF) Pen Crohns-UC-HS (PREFERRED NDCS STARTING WITH 00074)
- Humira(CF) Pen Pediatric UC (PREFERRED NDCS STARTING WITH 00074)
- Humira(CF) Pen Psor-Uv-Adol HS (PREFERRED NDCS STARTING WITH 00074)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another biologic DMARD or targeted synthetic DMARD. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous therapies tried |
| **Age Restrictions** | Crohn's disease (CD), 6 or older (initial therapy only). Ulcerative colitis (UC) 5 or older (initial therapy only), PP-18 or older (initial therapy only) |
| **Prescriber Restrictions** | Initial therapy only for all dx-RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist.UV-ophthalmologist |
| **Coverage Duration** | Approve through 12/31/24 |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. PP initial-approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. FDA approve indications cont tx - must respond to tx as determined by prescriber. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Clinical criteria incorporated into the Humira 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IBRANCE

## Products Affected

- Ibrance

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Breast cancer - approve recurrent or metastatic, hormone receptor positive (HR+) [i.e., estrogen receptor positive- [ER+] and/or progesterone receptor positive [PR+]] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, or letrozole 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND meets one of the following conditions: Ibrance will be used in combination with anastrozole, exemestane, or letrozole or Ibrance will be used in combination with fulvestrant 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Ibrance with be used in combination with anastrozole, exemestane or letrozole or Ibrance will be used in combination with fulvestrant 4. Pt is postmenopausal and Ibrance will be used in combination with fulvestrant. In addition, patients new to therapy must have a trial of Kisqali, Kisqali Femara Co-Pack or |

| PA Criteria | Criteria Details |
|---|---|
| | Verzenio prior to approval of Ibrance. Liposarcoma-approve if the patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Liposarcoma |
| **Part B Prerequisite** | No |

# ICATIBANT

## Products Affected

- icatibant
- Sajazir

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant - the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# ICLUSIG

## Products Affected

- Iclusig

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Patients new to therapy with Acute lymphoblastic leukemia, Philadelphia chromosome positive or chronic myeloid leukemia-approve if the patient has tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel. GIST - approve if the patient tried all of the FDA-approved therapies first to align with NCCN recommendations which include: Imatinib or Ayvakit (avapritinib tablets), AND Sunitinib or Sprycel (dasatinib tablets), AND Stivarga (regorafenib tablets), AND Qinlock (ripretinib tablets). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has ABL1 rearrangement or FGFR1 rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia |
| **Part B Prerequisite** | No |

# IDHIFA

## Products Affected

- Idhifa

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

# ILARIS

## Products Affected

- Ilaris (PF)

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

| PA Criteria | Criteria Details |
|---|---|
| | Actemra or Kineret OR 3. Pt has features of SJIA with active systemic features with concerns of progression to macrophage activation syndrome (MAS) [as determined by the prescribing physician] AND has tried Kineret. Still's Disease-Initial-approve if the patient has tried at least TWO other biologics or patient has features of poor prognosis and has tried Actemra or Kineret or patient has active systemic features with concerns of progression to macrophage activation syndrome (MAS) and has tried Kineret. Acute gout flare- approve if (i and ii): (i) pt has intolerance, contraindication, or lack of response to NSAIDs and colchicine for the treatment of acute gout flares OR pt is unable to be retreated with a repeat course of corticosteroids (oral or injectable) for acute gout flare, and (ii) patient is receiving or will be taking concomitant urate lowering medication for prevention of gout unless contraindicated (ex: allopurinol, febuxostat, probenecid). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IMATINIB

## Products Affected

- imatinib oral tablet 100 mg, 400 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. |
| **Age Restrictions** | ASM, DFSP, HES, MDS/MPD/Myeloid/Lymphoid Neoplasms-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For ALL/CML, must have Ph-positive for approval of imatinib.Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or according to the prescriber, the patient cannot take Turalio. Myelodysplastic/myeloproliferative disease-approve if the condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.Graft versus host disease, chronic-approve if the patient has tried at least one conventional systemic treatment (e.g., imbruvica). Metastatic melanoma-approve if the patient has c-Kit-positive advanced/recurrent or metastatic melanoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement or an FIP1L1-PDGFRA or PDGFRB rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | Chordoma, advanced, aggressive or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic. |
| **Part B Prerequisite** | No |

# IMBRUVICA

## Products Affected

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

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

| PA Criteria | Criteria Details |
|---|---|
| | Central nervous system Lymphoma (primary)- approve if the patient is not a candidate for or is intolerant to high-dose methotrexate OR has tried at least one therapy (e.g., methotrexate, rituximab, vincristine, procarbazine, cytarabine, thiotepa, carmustine, intrathecal methotrexate, cytarabine, or rituximab). Hairy Cell Leukemia - approve if the patient has tried at least two systemic regimens (cladribine, Nipent [pentostatin injection], rituximab, or Pegasys [peginterferon alfa-2a subcutaneous injection]). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma, Marginal Zone Lymphoma, Mantle Cell Lymphoma |
| **Part B Prerequisite** | No |

# IMJUDO

## Products Affected

- Imjudo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | HCC, Esophageal/Esophagogastric Junction Ca, Gastric Ca-30 days, NSCLC-6 months |
| **Other Criteria** | Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. HCC-approve if the patient has unresectable or metastatic disease or the patient is not a surgical candidate, Imjudo will be used as first-line systemic therapy in combination with Imfinzi. Non-Small Cell Lung Cancer-Approve if the patient meets ALL of the following criteria (A, B, and C ): A) Patient has recurrent, advanced, or metastatic disease, AND B) Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion), AND C) Patient meets ONE of the following (i, ii, iii, or iv): i. Patient meets BOTH of the following (a and b): a) The tumor is negative for actionable molecular markers-Note: Examples of actionable molecular markers include epidermal growth factor receptor (EGFR) mutations, anaplastic lymphoma kinase (ALK) genomic tumor aberrations, KRAS, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), AND b) Imjudo is used as first-line therapy, OR ii. Patient meets both of the following (a and b): a) The tumor is positive for ONE of the following [(1), (2), or (3)]: (1) Epidermal growth factor receptor (EGFR) exon 20 mutation positive, OR (2) KRAS G12C mutation positive, OR (3) ERBB2 (HER2) mutation positive, AND b) Imjudo is used as first-line therapy, OR |

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

# INGREZZA

## Products Affected

- Ingrezza
- Ingrezza Initiation Pack

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

# INJECTABLE TESTOSTERONE PRODUCTS

## Products Affected

- testosterone cypionate
- testosterone enanthate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, lab results |
| **Age Restrictions** | Delayed puberty or induction of puberty in males-14 years and older |
| **Prescriber Restrictions** | Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients. |
| **Coverage Duration** | Delayed puberty or induction of puberty in males-6 months, all others-12 months |
| **Other Criteria** | Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. Delayed puberty or induction of puberty in males - Approve testosterone enanthate. Breast cancer in females-approve testosterone enanthate. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual |

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

# INLYTA

## Products Affected

- Inlyta oral tablet 1 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Advanced Renal cell carcinoma-approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy. Soft tissue sarcoma-approve if the patient has alveolar soft part sarcoma and the medication will be used in combination with Keytruda (pembrolizumab). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma, Soft tissue sarcoma |
| **Part B Prerequisite** | No |

# INPEFA

## Products Affected

- Inpefa oral tablet 200 mg, 400 mg

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

# INQOVI

## Products Affected

- Inqovi

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

# INREBIC

## Products Affected

- Inrebic

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has intermediate-2 or high-risk disease. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Myeloid/Lymphoid Neoplasms with Eosinophilia |
| **Part B Prerequisite** | No |

# IRESSA

## Products Affected

- gefitinib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NSCLC-approve if the patient has advanced or metastatic disease and the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IVERMECTIN (ORAL)

## Products Affected

- ivermectin oral

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

# IVIG

## Products Affected

- Privigen

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

# IWILFIN

## Products Affected

- Iwilfin

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Neuroblastoma-Approve if the patient meets the following (A, B and C): A) Patient has high-risk disease, AND B) The medication is being used to reduce the risk of relapse, AND C) Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy. Note: Examples of anti-GD2 immunotherapy includes Unituxin (dinutuximab intravenous infusion). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# JAKAFI

## Products Affected

- Jakafi

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

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms |
| **Part B Prerequisite** | No |

# JAYPIRCA

## Products Affected

- Jaypirca oral tablet 100 mg, 50 mg

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

| PA Criteria | Criteria Details |
|---|---|
| | or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules). Richter's Transformation to DLBCL- pt has tried at least one chemotherapy regimen or is not a candidate for a chemotherapy regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Richter's Transformation to Diffuse Large B-Cell Lymphoma |
| **Part B Prerequisite** | No |

# JEMPERLI

## Products Affected

- Jemperli

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Endometrial cancer-approve if the patient has recurrent, advanced or metastatic disease. Mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) Solid tumors-approve if the patient has progressed on or after prior treatment and according to the prescriber, the patient does not have any satisfactory alternative treatment options. Small Bowel Adenocarcioma-approve if the patient has dMMR or MSI-H disease and has advanced or metastatic disease and Jemperli will be used as initial therapy when the patient has received adjuvant oxaliplatin or has a contraindication to oxaliplatin OR Jemperli is used as subsequent therapy and the patient has NOT received oxaliplatin in the adjuvant setting and the patient does NOT have a contraindication to oxaliplatin. Colon, Rectal, or Appendiceal Cancer-approve if patient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease AND has advanced or metastatic disease AND is being used for neoadjuvant therapy or primary or subsequent therapy. |

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

# JUXTAPID

## Products Affected

- Juxtapid

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist, an endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Patient must meet ALL of the following criteria: 1) Patient has had genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B APOB, PCSK9, or LDLRAP1 gene locus OR the patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) and had clinical manifestation of HoFH before the age of 10 years OR both parents of the patient had untreated (LDL-C levels or total cholesterol levels consistent with HeFH OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL and had clinical manifestation of HoFH before the age of 10 years OR both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with HeFH, AND 2) patient tried at least one PCSK9 inhibitor for greater than or equal to 8 continuous weeks and the LDL-C level after this PCSK9 inhibitor therapy remains greater than or equal to 70 mg/dL OR the patient is known to have two LDL-receptor negative alleles, AND 3) Patient has tried one high-intensity statin therapy (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than 20 mg daily [as a single-entity or as a combination product]) and the LDL-C level after these |

| PA Criteria | Criteria Details |
|---|---|
| | treatment regimens remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or patient experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KADCYLA

## Products Affected

- Kadcyla

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

# KALYDECO

## Products Affected

- Kalydeco

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

# KANUMA

## Products Affected

- Kanuma

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

# KERENDIA

## Products Affected

- Kerendia

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

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

# KESIMPTA

## Products Affected

- Kesimpta Pen

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

# KEYTRUDA

## Products Affected

- Keytruda

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

# KIMMTRAK

## Products Affected

- Kimmtrak

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

# KISQALI

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Breast cancer - approve recurrent or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and Kisqali (not Co-Pack) will be used in |

| PA Criteria | Criteria Details |
|---|---|
| | combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole. 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. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Pre/peri-menopausal women with breast cancer in combination with fulvestrant, and endometrial cancer |
| **Part B Prerequisite** | No |

# KORLYM

## Products Affected

- Korlym
- mifepristone oral tablet 300 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior surgeries |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome |
| **Coverage Duration** | Endogenous Cushing's Synd-1 yr. Patients awaiting surgery or response after radiotherapy-4 months |
| **Other Criteria** | Under CMS Review |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Patients with Endogenous Cushing's Syndrome, awaiting surgery. Patients with Endogenous Cushing's syndrome, awaiting a response after radiotherapy |
| **Part B Prerequisite** | No |

# KOSELUGO

## Products Affected

- Koselugo

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

| PA Criteria | Criteria Details |
|---|---|
| | lesions, OR iv. Patient has central nervous system disease, AND B) The medication is used as a single agent. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Circumscribed Glioma, Langerhans Cell Histiocytosis |
| **Part B Prerequisite** | No |

# KRAZATI

## Products Affected

- Krazati

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine. Colon or Rectal Cancer-approve if pt has unresectable, advanced, or metastatic disease AND pt has KRAS G12C mutation-positive disease AND medication is prescribed as part of a combination regimen or the patient is unable to tolerate combination therapy AND pt has has previously received a chemotherapy regimen for colon or rectal cancer. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

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

# LANREOTIDE

## Products Affected

- Somatuline Depot

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, previous treatments/therapies |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescribed by or in consultation with an endo/onc/neuro. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Acromegaly-approve if the patient has (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. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | Pheochromocytoma/paraganglioma |
| **Part B Prerequisite** | No |

# LAPATINIB

## Products Affected

- lapatinib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis for which lapatinib is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status. |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | HER2-positive recurrent or metastatic breast cancer, approve if lapatinib will be used in combination with capecitabine OR trastuzumab and the patient has tried at least two prior anti-HER2 based regimens OR the medication will be used in combination with an aromatase inhibitor and and the patient has HR+ dusease and the patient is a postmenopausal woman or the patient is premenopausal or perimenopausal woman and is receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian irradiation OR the patient is a man and is receiving a GnRH analog. Colon or rectal cancer-approve if the patient has unresectable advanced or metastatic disease that is human epidermal receptor 2 (HER2) amplified and with wild-type RAS and BRAF disease and the patient has tried at least one chemotherapy regimen or is not a candidate for intensive therapy and the medication is used in combination with trastuzumab (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan) and the patient has not been previously treated with a HER2-inhibitor. Bone Cancer-approve if the patient has recurrent chordoma and if the patient has epidermal growth-factor receptor (EGFR)-positive disease. |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Bone cancer-chordoma, colon or rectal cancer, breast cancer in pre/peri-menopausal women and men |
| **Part B Prerequisite** | Yes |

# LENALIDOMIDE

## Products Affected

- lenalidomide

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and previous therapies or drug regimens tried. |
| **Age Restrictions** | 18 years and older (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma) |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Follicular lymphoma-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one prior therapy. MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one other therapy or therapeutic regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). B-cell-lymphoma (other)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia and the pt has serum erythropoietin levels greater than or equal to 500 mU/mL or according to the prescriber the patient has anemia, has serum erythropoietin levels less than 500 mU/mL and patient has experienced no response or loss of response to erythropoietic stimulating agents. Peripheral T-Cell Lymphoma or T-Cell |

| PA Criteria | Criteria Details |
|---|---|
| | Leukemia/Lymphoma-approve if the pt has tried at least one other therapy or regimen. CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-approve if the patient has tried at least three other regimens. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide is used in combination with dexamethasone. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system Lymphoma, Kaposi's sarcoma. |
| **Part B Prerequisite** | No |

# LENVIMA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | DTC - must be refractory to radioactive iodine treatment for approval. RCC - approve if the pt meets ALL of the following criteria: 1) pt has advanced disease AND if the patient meets i or ii-i. Lenvima is is being used in combination with Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b-a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND B) The medication is used in combination with Keytruda (pembrolizumab for intravenous injection) AND C)the disease has progressed on at least one prior systemic therapy AND D) The patient is not a candidate for curative surgery or radiation. HCC-approve if the patient has unresectable or metastatic disease. Thymic carcinoma-approve if the patient has tried at least one chemotherapy |

| PA Criteria | Criteria Details |
|---|---|
| | regimen. Melanoma - approve if the patient has unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Renal cell carcinoma with non-clear cell histology and Melanoma |
| **Part B Prerequisite** | No |

# LEUKINE

## Products Affected

- Leukine injection recon soln

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | AML if prescribed by or in consultation with an oncologist or hematologist, PBPC/BMT - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation, Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome.Neuroblastoma-prescribed by or in consultation with an oncologist. |
| **Coverage Duration** | Radiation Syndrome/BMT - 1 mo, AML/Neuroblastoma-6 months, PBPC-14 days |
| **Other Criteria** | Neuroblastoma-approve if the patient is receiving Leukine in a regimen that recommends administration in combination with a granulocyte-macrophage colony stimulating factor (examples: dinutuximab or naxitamab). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Neuroblastoma |
| **Part B Prerequisite** | No |

# LIBTAYO

## Products Affected

- Libtayo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, previous surgeries or radiation |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. CSCC-approve if the patient meets one of the following (i or ii): (i): pt has has locally advanced, recurrent, or metastatic disease and is not a candidate for curative surgery or curative radiation or (ii): pt has very-high risk, locally advanced, unresectable, or regional disease and this medication will be used as neoadjuvant therapy. Basal Cell Carcinoma-approve if the patient has locally advanced, nodal or metastatic disease. NSCLC-approve if the patient has recurrent, advanced, or metastatic disease. Cervical cancer-approve if pt has local or regional recurrence or distant metastic disease AND this medication is used as subsequent therapy. Vulvar cancer-approve if pt has advanced, recurrent, or metastatic disease AND this medication is used as subsequent therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Cervical cancer, vulvar cancer |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# LIDOCAINE PATCH

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 12 months |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Diabetic neuropathic pain, chronic back pain |
| **Part B Prerequisite** | No |

# LONG ACTING OPIOIDS

## Products Affected

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

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

| PA Criteria | Criteria Details |
|---|---|
| | not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LONSURF

## Products Affected

- Lonsurf

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Gastric or Gas)troesophageal Junction Adenocarcinoma, approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma. Colon and rectal cancer-approve per labeling if the patient has been previously treated with a fluropyrimidine, oxaliplatin, 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** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.Nasopharyngeal carcinoma- approve if the patient has recurrent, unresectable, oligometastatic, or metastatic disease AND the patient meets ONE of the following (i or ii): i. Patient meets BOTH of the following (a and b): a) Loqtorzi is used for first-line treatment AND b) Loqtorzi is used in combination with cisplatin and gemcitabine, OR ii. Patient meets both of the following (a and b): a) Loqtorzi is used for subsequent treatment AND b) Loqtorzi is used as a single agent. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LORBRENA

## Products Affected

- Lorbrena oral tablet 100 mg, 25 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, ALK status, ROS1 status, previous therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Erdheim Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has IMT with ALK translocation. NSCLC - Approve if the patient has ALK-positive advanced or metastatic NSCLC, as detected by an approved test. In addition, patients new to therapy must also have a trial of Alecensa prior to approval of Lorbrena. NSCLC-ROS1 Rearrangement-Positive, advanced or metastatic NSCLC-approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive, Erdheim Chester Disease, Inflammatory Myofibroblastic Tumor (IMT) |
| **Part B Prerequisite** | No |

# LUMAKRAS

## Products Affected

- Lumakras

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease, as determined by an approved test AND either (i or ii): (i) patient has locally advanced or metastatic disease and has been previously treated with at least one systemic regimen OR (ii) patient has recurrent disease after resection. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Pancreatic Adenocarcinoma |
| **Part B Prerequisite** | No |

# LUMIZYME

## Products Affected

- Lumizyme

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

# LUNSUMIO

## Products Affected

- Lunsumio

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

# LUPRON DEPOT 7.5MG

## Products Affected

- Lupron Depot

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Premenstrual disorders - 18 years and older |
| **Prescriber Restrictions** | Prostate cancer-prescr/consult with oncologist or urologist. For the treatment of other cancer diagnosis must be prescribed by or in consultation with an oncologist. |
| **Coverage Duration** | uterine leiomyomata 3 mo.All other=12 mo |
| **Other Criteria** | For a diganosis of prostate cancer, patients are required to try Orgovyx or Eligard prior to approval. Premenstrual disorders including PMS and PMDD- approve if pt has severe refractory premenstrual symptoms AND pt has tried an SSRI or combined oral contraceptive. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Ovarian cancer including fallopian tube and primary peritoneal cancer, breast cancer, prophylaxis or treatment of uterine bleeding or menstrual suppression in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors, premenstrual disorders including premenstrual syndrome and premenstrual dysphoric disorder, uterine cancer |
| **Part B Prerequisite** | No |

# LYNPARZA

## Products Affected

- Lynparza

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient meets one of the following criteria (A or B): A) The patient meets both of the following criteria for first-line maintenance therapy (i and ii): i. The patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND ii. The patient is in complete or partial response to first-line platinum-based chemotherapy regimen (e.g., carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin) OR B) The patient is in complete or partial response after at least two platinum-based chemotherapy regimens (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast |

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

# LYTGOBI

## Products Affected

- Lytgobi

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

# MARGENZA

## Products Affected

- Margenza

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

# MEGESTROL

## Products Affected

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

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

# MEKINIST

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations |
| **Age Restrictions** | 1 year and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Melanoma must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC requires BRAF V600E Mutation and use in combination with Tafinlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafinlar, unless intolerant AND the patient has BRAF V600-positive disease. Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for low-grade serous carcinoma or the patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafinlar. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation postive disease and the medication will be taken in combination with Tafinlar. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) |

| PA Criteria | Criteria Details |
|---|---|
| | Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma OR iii. Melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Tafinlar (dabrafenib). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR patient has Erdheim Chester disease or Rosai-Dorfman disease. Metastatic or Solid Tumors-Approve if the patient meets the following (A, B, and C): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafinlar (dabrafenib capsules), AND C) Patient has no satisfactory alternative treatment options. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Histiocytic Neoplasm. |
| **Part B Prerequisite** | No |

# MEKTOVI

## Products Affected

- Mektovi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, BRAF V600 status, concomitant medications |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. Histiocytic neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. multisystem disease OR, ii. pulmonary disease or, iii. central nervous system lesions. NSCLC-approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Braftovi (encorafenib capsules). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Histiocytic Neoplasms |
| **Part B Prerequisite** | No |

# MEMANTINE

## Products Affected

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

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

# MEPSEVII

## Products Affected

- Mepsevii

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

# METHYLERGONOVINE

## Products Affected

- methylergonovine oral

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

# MODAFINIL/ARMODAFINIL

## Products Affected

- armodafinil
- modafinil oral tablet 100 mg, 200 mg

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

# MONJUVI

## Products Affected

- Monjuvi

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

# MYALEPT

## Products Affected

- Myalept

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an endocrinologist or a geneticist physician specialist |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MYFEMBREE

## Products Affected

- Myfembree

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

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# NAGLAZYME

## Products Affected

- Naglazyme

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

# NAYZILAM

## Products Affected

- Nayzilam

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

# NERLYNX

## Products Affected

- Nerlynx

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

# NEXLETOL

## Products Affected

- Nexletol

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

| PA Criteria | Criteria Details |
|---|---|
| | trials the skeletal-related symptoms resolved during discontinuation. Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt meets all of the following: Pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, CAD, PAD, undergone a coronary or other arterial revascularization procedure, AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NEXLIZET

## Products Affected

- Nexlizet

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

| PA Criteria | Criteria Details |
|---|---|
| | during discontinuation. Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt meets all of the following: Pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, CAD, PAD, undergone a coronary or other arterial revascularization procedure, AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# 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 |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | MM - be used in combination with lenalidomide or cyclophosphamide OR pt had received at least ONE previous therapy for multiple myeloma OR the agent will be used following autologous stem cell transplantation (ASCT). Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma-approve if used in combination with a rituximab product and dexamethasone (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma |
| **Part B Prerequisite** | Yes |

# NITISINONE

## Products Affected

- nitisinone

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

# NIVESTYM

## Products Affected

- Nivestym

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation. SCN- hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. |
| **Coverage Duration** | chemo/SCN/AML-6mo.HIV/AIDS-4mo.MDS-3mo.PBPC,Drug induce A/N,ALL,BMT-3mo. Radi-1mo. Other=12mo. |
| **Other Criteria** | Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or |

| PA Criteria | Criteria Details |
|---|---|
| | frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Acute lymphocytic leukemia (ALL), Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome) |
| **Part B Prerequisite** | No |

# NON-INJECTABLE TESTOSTERONE PRODUCTS

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients. |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary |

| PA Criteria | Criteria Details |
|---|---|
| | or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note:  For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization) |
| **Part B Prerequisite** | No |

# NUBEQA

## Products Affected

- Nubeqa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) agonist or if the patient has had a bilateral orchiectomy or if the medication is used concurrently with Firmagon. Prostate cancer-metastatic, castration sensitive-approve if (A and B): A) the medication is used in combination with docetaxel or patient has completed docetaxel therapy, and B) the medication will be used in combination with a GnRH agonist or in combination with Firmagon or if the patient had a bilateral orchiectomy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NUCALA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another monoclonal antibody therapy. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Asthma-6 years of age and older. EGPA/Polyps-18 years of age and older. HES-12 years and older. |
| **Prescriber Restrictions** | Asthma-Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA-prescribed by or in consultation with an allergist, immunologist, pulmonologist or rheumatologist. HES-prescribed by or in consultation with an allergist, immunologist, hematologist, pulmonologist or rheumatologist. Polyps-prescribed by or in consult with allergist, immunologist or Otolaryngologist. |
| **Coverage Duration** | Initial-Asthma/EGPA/polyps-6 months, HES-8 months. 12 months continuation. |
| **Other Criteria** | Asthma initial - must have blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks (prior to tx with Nucala or another monoclonal antibody therapy that may lower blood eosinophil levels) AND has received combo tx w/inhaled corticosteroid AND at least 1 additional asthma controller/maintenance med (Examples: LAMA, LABA, leukotriene receptor antagonist, monoclonal antibody) AND pt's asthma cont to be uncontrolled, or was uncontrolled prior to starting Nucala or another monoclonal antibody therapy for asthma as defined by 1 of following-pt experi 2 or more asthma exacer req tx w/systemic corticosteroids in prev yr, pt experienced 1 or more asthma exacer requiring hospitalization, urgent care visit or ED visit in the prev yr, pt has a FEV1 less than 80 percent predicted, Pt has FEV1/FVC  less than |

| PA Criteria | Criteria Details |
|---|---|
| | 0.80, or Pt's asthma worsens upon taper of oral (systemic) corticosteroid therapy. Cont-pt responded to Nucala tx as determined by the prescribing physician AND Pt cont to receive tx with an inhaled corticosteroid. EGPA initial-approve if pt has active, non-severe disease, has/had a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks or within 6 wks prior to any monoclonal antibody that may lower blood eosinophil levels. Cont-pt responded to Nucala tx as determined by the prescribing physician.HES initial-pt has had hypereosinophilic synd for greater than or equal to 6 months AND has FIP1L1-PDGFRalpha-negative dis AND pt does NOT have identifiable non-hematologic secondary cause of hypereosinophilic synd AND prior to initiating tx with monoclonal antibody that may lower blood eosinophil levels, pt has/had a blood eosinophil level of greater than or equal to 1,000 cells per microliter. Cont-approve if the patient has responded to Nucala tx. Nasal polyps, initial-approve if pt meets ALL of the following criteria(A, B, C and D):A) pt has chronic rhinosinusitis w/nasal polyposis as evidenced by direct examination, endoscopy, or sinus CT scan AND B)pt experienced 2 or more of the following sympt for at least 6 months:nasal congest/obstruct/discharge, and/or reduction/loss of smell AND C)pt meets BOTH of the following (a and b): a)Pt has received tx with intranasal corticosteroid AND b)Pt will continue to receive tx with intranasal corticosteroid concomitantly with Nucala AND D)pt meets 1 of the following (a, b or c): a)Pt has received at least 1 course of tx with a systemic corticosteroid for 5 days or more within the previous 2 years, OR b)Pt has a contraindication to systemic corticosteroid tx, OR c)Pt had prior surgery for nasal polyps.Cont-approve if the pt has received at least 6 months of therapy, continues to receive tx with an intranasal corticosteroid and has responded to tx. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NUEDEXTA

## Products Affected

- Nuedexta

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

# NUPLAZID

## Products Affected

- Nuplazid

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

# NURTEC

## Products Affected

- Nurtec ODT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention if Nurtec ODT is being taking for the preventive treatment of episodic migraine. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Migraine, Acute treatment-approve if the patient has tried at least one triptan or has a contraindication to triptans. Preventive treatment of episodic migraine-approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication and has tried at least two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has experienced adverse events severe enough to warrant discontinuation. A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try two standard prophylactic pharmacologic therapies. In addition, if the patient is currently taking Nurtec ODT, the patient has had a significant clinical benefit from the medication. |
| **Indications** | All FDA-approved Indications. |

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

# NYVEPRIA

## Products Affected

- Nyvepria

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

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

# OCALIVA

## Products Affected

- Ocaliva

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber specialty, lab values, prior medications used for diagnosis and length of trials |
| **Age Restrictions** | 18 years and older (initial) |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial) |
| **Coverage Duration** | 6 months initial, 1 year cont. |
| **Other Criteria** | Initial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following:a)Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b)Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative c)Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)). Patients new to therapy and continuing therapy must not have cirrhosis or must have compensated cirrhosis without evidence of portal hypertension. |
| **Indications** | All FDA-approved Indications. |

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

# OCTREOTIDE INJECTABLE

## Products Affected

- octreotide acetate

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

# ODOMZO

## Products Affected

- Odomzo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | BCC - Must not have had disease progression while on Erivedge (vismodegib). |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metastatic BCC - approve, if the disease is limited to nodal metastases. (Note-This includes primary or recurrent nodal metastases. A patient with distant metastasis does not meet this requirement.) |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Metastatic BCC |
| **Part B Prerequisite** | No |

# OFEV

## Products Affected

- Ofev

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | IPF - must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. Interstitial lung disease associated with systemic sclerosis-approve if the FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography. Chronic fibrosing interstitial lung disease-approve if the forced vital capacity is greater than or equal to 45 percent of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10 percent of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# OJJAARA

## Products Affected

- Ojjaara

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Myelofibrosis-approve if the patient has intermediate-risk or high-risk disease and (a or b): a) the patient has anemia, defined as hemoglobin less than 10g/dL or b) the patient has platelet count greater than or equal to 50x109/L. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ONUREG

## Products Affected

- Onureg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | AML - Approve if the medication is used for post-remission maintenance therapy AND the patient has intermediate or poor-risk cytogenetics OR has complete response to previous intensive induction chemotherapy AND the patient has declined or is not fit or eligible for allogeneic hematopoietic stem cell transplant. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OPDIVO

## Products Affected

- Opdivo

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

# OPDUALAG

## Products Affected

- Opdualag

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

# OPSUMIT

## Products Affected

- Opsumit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | PAH WHO group, right heart catheterization results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist. |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Pulmonary arterial hypertension (PAH) WHO Group 1 patients are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORENCIA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial therapy only-RA and JIA/JRA prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). PsA, initial -approve. Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], initial - approve if the patient has tried one other agent for this condition or the patient will be starting on Orencia concurrently with methotrexate, sulfasalazine or leflunomide or the patient has an absolute contraindication to methotrexate, sulfasalazine or leflunomide or the patient has aggressive disease as determined by the prescribing physician. Cont tx - responded to therapy as per the prescriber. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# ORGOVYX

## Products Affected

- Orgovyx

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

# ORKAMBI

## Products Affected

- Orkambi oral granules in packet
- Orkambi oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination use with Kalydeco, Trikafta or Symdeko. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 1 year of age and older |
| **Prescriber Restrictions** | prescribed by or in consultation with a pulmonologist or a physician who specializes in CF |
| **Coverage Duration** | 1 year |
| **Other Criteria** | CF - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation) |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORSERDU

## Products Affected

- Orserdu oral tablet 345 mg, 86 mg

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

# OTEZLA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD). |
| **Required Medical Information** | Diagnosis, previous drugs tried |
| **Age Restrictions** | 18 years and older (initial) |
| **Prescriber Restrictions** | All dx-initial only-PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist. Behcet's-prescribed by or in consultation with a dermatologist or rheumatologist |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | PP initial-approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. PsA initial-approve. Behcet's-patient has oral ulcers or other mucocutaneous involvement AND patient has tried at least ONE other systemic therapy. PsA/PP/Behcet's cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# OXERVATE

## Products Affected

- Oxervate

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

# PADCEV

## Products Affected

- Padcev

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Urothelial carcinoma-approve if the patient has locally advanced or metastatic disease and meets either (i or ii): (i): Padcev is used as first-line therapy and will be used in combination with Keytruda (pembrolizumab intravenous infusion), or (ii): Padcev is used as subsequent therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PANRETIN

## Products Affected

- Panretin

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

# PEMAZYRE

## Products Affected

- Pemazyre

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

# PENICILLAMINE

## Products Affected

- penicillamine oral tablet

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

# PHENYLBUTYRATE

## Products Affected

- sodium phenylbutyrate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant therapy with more than one phenylbutyrate product |
| **Required Medical Information** | Diagnosis, genetic tests and lab results (as specified in the Other Criteria field) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases) |
| **Coverage Duration** | Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval |
| **Other Criteria** | Urea cycle disorders-approve if genetic testing confirmed a mutation resulting in a urea cycle disorder or if the patient has hyperammonemia diagnosed with an ammonia level above the upper limit of the normal reference range for the reporting laboratory. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PHEOCHROMOCYTOMA

## Products Affected

- metyrosine

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

# PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

## Products Affected

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

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

# PIQRAY

## Products Affected

- Piqray

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, E and F): A) The patient is a postmenopausal female, male or pre/perimenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene or fulvestrant) AND F) Piqray will be used in combination with fulvestrant injection. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Treatment of breast cancer in premenopausal women |
| **Part B Prerequisite** | No |

# PIRFENIDONE

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | IPF - must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PLEGRIDY

## Products Affected

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

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

# POLIVY

## Products Affected

- Polivy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-cell lymphoma/High-Grade B-Cell Lymphoma-Approve if the patient has International Prognostic Index score of greater than or equal to 2 and will use Polivy as first line therapy OR the patient has been treated with at least one prior chemotherapy regimen. B-Cell Lymphoma (Examples include follicular lymphoma, AIDS-related B-cell lymphoma, post-transplant lymphoproliferative disorders, histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma) - approve if the patient has been treated with at least one prior chemotherapy regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | B-Cell Lymphoma |
| **Part B Prerequisite** | No |

# POMALYST

## Products Affected

- Pomalyst

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Kaposi Sarcoma/MM-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | CNS Lymphoma-approve if the patient has relapsed or refractory disease. Kaposi Sarcoma-Approve if the patient meets one of the following (i or ii): i. patient is Human Immunodeficiency Virus (HIV)-negative OR ii. patient meets both of the following (a and b): a) The patient is Human Immunodeficiency Virus (HIV)-positive AND b) The patient continues to receive highly active antiretroviral therapy (HAART). MM-approve if the patient has received at least one other Revlimid (lenalidomide tablets)-containing regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma |
| **Part B Prerequisite** | No |

# POSACONAZOLE (ORAL)

## Products Affected

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

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

# POTELIGEO

## Products Affected

- Poteligeo

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

# PREVYMIS

## Products Affected

- Prevymis intravenous
- Prevymis oral

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

# PROLIA

## Products Affected

- Prolia

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

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

# PROMACTA

## Products Affected

- Promacta

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

| PA Criteria | Criteria Details |
|---|---|
| | immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Thrombocytopenia in Myelodysplastic Syndrome (MDS) |
| **Part B Prerequisite** | No |

# PYRIMETHAMINE

## Products Affected

- pyrimethamine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient's immune status (Toxoplasma gondii Encephalitis, chronic maintenance and prophylaxis, primary) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis |
| **Part B Prerequisite** | No |

# QINLOCK

## Products Affected

- Qinlock

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Gastrointestinal stromal tumor (GIST)-approve if the patient has tried imatinib or avapritinib tablets, AND the patient meets one of the following criteria (i, ii, or iii): i. Patient has tried sunitinib and regorafenib tablets, OR ii. Patient has tried dasatinib tablets, OR iii. Patient is intolerant of sunitinib. Melanoma, cutaneous-approve if the patient has metastatic or unresectable disease, AND the patient has an activating KIT mutation, AND the patient has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Melanoma, cutaneous |
| **Part B Prerequisite** | No |

# QULIPTA

## Products Affected

- Qulipta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Preventive treatment of episodic migraine-approve if the patient has greater than or equal to 4 and less than 15 migraine headache days per month (prior to initiating a migraine-preventative medication). Chronic migraine prevention-approve if the patient has greater than or equal to 15 migraine headache days per month (prior to initiating a migraine-preventative medication). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RADICAVA ORS

## Products Affected

- Radicava ORS
- Radicava ORS Starter Kit Susp

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | ALSFRS-R score, FVC %, time elapsed since diagnosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS (initial and continuation). |
| **Coverage Duration** | Initial, 6 months. Continuation, 6 months |
| **Other Criteria** | ALS, initial therapy - approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, based on the application of the El Escorial or the revised Airlie house diagnostic criteria AND 2. Patient has a score of two points or more on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. Patient has a percent predicted FVC greater than or equal to 80% (ie, has normal respiratory function), AND 4. Patient has been diagnosed with ALS for less than or equal to 2 years. 5. Patient has received or is currently receiving riluzole tablets. Note-a trial of Tiglutik or Exservan would also count. ALS, continuation therapy - approve if, according to the prescribing physician, the patient continues to benefit from therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# RECLAST

## Products Affected

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

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

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

# REMICADE

## Products Affected

- Remicade

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Biologic DMARD or Targeted Synthetic DMARD |
| **Required Medical Information** | Diagnosis, concurrent medication, previous medications tried |
| **Age Restrictions** | All dx-initial therapy only-Prescribed by or in consult w/RA/AS/Still's/JIA/JRA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's- rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarcoidosis-pulmonol, ophthalmol, or dermatol, cardio/neuro. |
| **Prescriber Restrictions** | All dx-initial therapy only-Prescribed by or in consult w/RA/AS/Still's/JIA/JRA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's- rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarcoidosis-pulmonol, ophthalmol, or dermatol, cardio/neuro. |
| **Coverage Duration** | FDAind ini-3 mo,cont1yr,GVHD ini-1 mo,cont-3 mo,Pyo Gang-ini4 mo,cont1 yr,others-ini 3mo,cont-12 mo |
| **Other Criteria** | RA initial, pt has tried 1 conventional synthetic DMARD for at least 3 months (note:  pts who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). CD approve if the pt has tried corticosteroid (CS) or if CSs contraindicated or if currently on CS or if the patient has tried one other aconventional systemic therapy for CD OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had |

| PA Criteria | Criteria Details |
|---|---|
| | ileocolonic resection.Note-a previous trial of a biologic also counts as a trial of one other agent for CD. Ulcerative colitis (UC).Tried one systemic agent or was intolerant to one of these agents OR the patient has pouchitis AND has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Note-a previous trial of a biologic also counts as a trial of one systemic agent for UC. Behcet's.Pt has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa). NOTE: An exception to the requirement for a trial of one conventional therapy can be made if the patient has already had a trial of at least one tumor necrosis factor for Behcet's disease. These patients who have already tried a biologic for Behcet's disease are not required to "step back" and try a conventional therapy) OR has ophthalmic manifestations. SD.Tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant.Prev trial of one biologic other than requested drug or biosimilar of the requested drug also counts.UV.Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab. Prev trial of one biologic other than requested drug or biosimilar of the requested drug also counts. Sarcoidosis.Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG).Tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Hidradenitis suppurativa (HS).Tried 1 tx (eg, intralesional/oral CS, systemic antibiotic, isotretinoin).GVHD.Tried one conventional systemic treatment (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.). JIA (regardless of type of onset) approve if pt has tried 1 other agent for this condition (eg, MTX, sulfasalazine, or leflunomide, an NSAID, or one biologic DMARD [eg, Humira, Orencia, Enbrel, Kineret, Actemra]) or the pt has aggressive disease. PP- approve if the patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant or the patient has a contraindication to methotrexate (MTX), as determined by the prescriber.Note-a previous trial of a biologic also counts as a trial of a systemic agent. cont tx - approve if patient has had a response, as determined by the prescriber. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Juvenile Idiopathic Arthritis (JIA). Sarcoidosis |
| **Part B Prerequisite** | No |

# REMODULIN

## Products Affected

- treprostinil sodium

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with Other Oral or Inhaled Prostacyclin Agents Used for Pulmonary Hypertension. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH WHO Group 1, prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation). |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Pulmonary Arterial Hypertension (PAH) [World Health Organization (WHO) Group 1], Initial Therapy-Approve if the patient meets all of the following criteria (i, ii, iii, and iv): i. Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH), AND ii. Patient meets the following criteria (a and b): a) Patient has had a right heart catheterization, AND b) Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH, AND iii. Patient meets ONE of the following criteria (a or b): a) Patient is in Functional Class III or IV, OR b) Patient is in Functional Class II and meets ONE of the following criteria [(1) or (2)]: (1) Patient has tried or is currently receiving one oral agent for PAH, OR (2) Patient has tried one inhaled or parenteral prostacyclin product for PAH, AND iv. Patient with idiopathic PAH must meet ONE of the following criteria (a, b, c, d, or e): a) Patient meets both of the following criteria [(1) and (2)]: (1) the patient has had an acute response to vasodilator testing that occurred during the right heart catheterization, AND (2) Patient has tried one calcium channel blocker (CCB) therapy, OR b) According to the |

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

# REPATHA

## Products Affected

- Repatha
- Repatha Pushtronex
- Repatha SureClick

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use of Leqvio or Praluent. |
| **Required Medical Information** | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field) |
| **Age Restrictions** | ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older. |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders |
| **Coverage Duration** | Approve for 1 year |
| **Other Criteria** | Hyperlipidemia with HeFH - approve if: pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the symptoms resolved upon discontinuation. Hyperlipidemia with ASCVD -approve if: 1) has one of the following conditions: prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, CAD, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) tried ONE high intensity statin (defined above) and LDL remains 70 mg/dL or higher unless pt is statin intolerant (defined above). HoFH - approve if: 1) has one of the following: a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha or Juxtapid), OR d) has |

| PA Criteria | Criteria Details |
|---|---|
| | clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity statin (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)- approve if all of the following are met: 1) coronary artery calcium or calcification (CAC) score 300 Agatston units or higher, AND 2) tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RETEVMO

## Products Affected

- Retevmo oral capsule 40 mg, 80 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Medullary Thyroid Cancer/Thyroid Cancer-12 years and older, all others 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has recurrent, advanced or metastatic disease AND the tumor is RET fusion-positive. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion positive or RET mutation positive disease AND the patient meets i or ii: i. patient has anaplastic thyroid cancer OR ii. the disease requires treatment with systemic therapy and patient has medullary thyroid cancer or the disease is radioactive iodine-refractory. Solid tumors-approve if the patient has recurrent, advanced or metastatic disease and the tumor is rearranged during transfection (RET) fusion-positive. Histiocytic neoplasm-approve if the patient has a rearranged during transfection (RET) fusion and has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Anaplastic thyroid carcinoma, histiocytic neoplasm |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# REVCOVI

## Products Affected

- Revcovi

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

# 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 |
|---|---|
| **Exclusion Criteria** | Concurrent use with a biologic or with a targeted synthetic DMARD, Concurrent use with other potent immunosuppressants, Concurrent use with an anti-interleukin monoclonal antibody, Concurrent use with other janus kinase inhibitors, or concurrent use with a biologic immunomodulator. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | PsA/RA/UC/AS/CD-18 years and older (initial therapy), AD-12 years and older (initial therapy) |
| **Prescriber Restrictions** | RA/AS/Non-Radiographic Spondy, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or derm. UC/CD-prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | RA/PsA/UC/AS/CD initial-approve if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AD-approve if the patient has had a 3 month trial of at least one traditional systemic therapy or has tried at least one traditional systemic therapy but was unable to tolerate a 3 month trial. Note: Examples of traditional systemic therapies include azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis. Non-Radiographic Axial Spondyloarthritis-approve if the patient has objective signs of inflammation |

| PA Criteria | Criteria Details |
|---|---|
| | defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroiliitis reported on MRI and patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3- month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ROFLUMILAST (ORAL)

## Products Affected

- roflumilast

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Obstructive Pulmonary Disease (COPD), medications tried. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | COPD, approve in patients who meet all of the following conditions: Patients has severe COPD or very severe COPD, AND Patient has a history of exacerbations, AND Patient has tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, indacaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ROZLYTREK

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | NSCLC-18 years and older, Solid Tumors-1 month and older, Pediatric Diffuse High-Grade Glioma-less than 18 years old |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Solid Tumors-Approve if the patient's tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease and the mutation was detected by an approved test. Pediatric Diffuse High-Grade Glioma- approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used either as adjuvant therapy or for recurrent or progressive disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Pediatric Diffuse High-Grade Glioma |
| **Part B Prerequisite** | No |

# RUBRACA

## Products Affected

- Rubraca

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient is in complete or partial response after a platinum-based chemotherapy regimen and the patient is in complete or partial response to first-line primary treatment or if the patient has recurrent disease and has a BRCA mutation. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy AND D) The patient meets one of the following criteria (i or ii): i. The patient has been previously treated with at least one taxane-based chemotherapy OR ii. The patient is not a candidate or is intolerant to taxane-based chemotherapy. 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 |

| PA Criteria | Criteria Details |
|---|---|
| | chemotherapy. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma |
| **Part B Prerequisite** | No |

# RUFINAMIDE

## Products Affected

- rufinamide

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

# RUXIENCE

## Products Affected

- Ruxience

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

# RYBREVANT

## Products Affected

- Rybrevant

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

# RYDAPT

## Products Affected

- Rydapt

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For AML, FLT3 status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | AML -approve if the patient is FLT3-mutation positive as detected by an approved test. Myeloid or lymphoid Neoplasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Myeloid or lymphoid Neoplasms with eosinophilia |
| **Part B Prerequisite** | No |

# RYLAZE

## Products Affected

- Rylaze

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

# SANDOSTATIN LAR

## Products Affected

- SANDOSTATIN LAR DEPOT INTRAMUSCULAR SUSPENSION, EXTENDED RELEASE RECON

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, previous treatments/therapies |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Acromegaly-prescr/consult w/endocrinologist. All neuroendocrine tumors-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist or neurosurgeon.Thymoma/Thymic carcinoma-prescr/consult w/oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Acromegaly-approve if the patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas)-approve. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

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

# SAPROPTERIN

## Products Affected

- sapropterin

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Palynziq |
| **Required Medical Information** | Diagnosis, Phe concentration |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy) |
| **Coverage Duration** | Initial-12 weeks, Continuation-1 year |
| **Other Criteria** | Initial - approve. Continuation (Note-if the patient has received less than 12 weeks of therapy or is restarting therapy with sapropterin should be reviewed under initial therapy) - approve if the patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescribing physician OR patient had a 20 percent or greater reduction in blood Phe concentration from baseline OR treatment with sapropterin has resulted in an increase in dietary phenylalanine tolerance. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SARCLISA

## Products Affected

- Sarclisa

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

# SCEMBLIX

## Products Affected

- Scemblix oral tablet 20 mg, 40 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Chronic Myeloid Leukemia (CML)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i or ii): i. The chronic myeloid leukemia is T315I-positive, OR ii. Patient has tried at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia. Note: Examples of tyrosine kinase inhibitors include imatinib tablets, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), Sprycel (dasatinib tablets), and Tasigna (nilotinib capsules). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has an ABL1 rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Myeloid/Lymphoid Neoplasms with Eosinophilia |
| **Part B Prerequisite** | No |

# SIGNIFOR

## Products Affected

- Signifor

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

# SIRTURO

## Products Affected

- Sirturo

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

# SKYRIZI

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) |
| **Required Medical Information** | Diagnosis, Previous medication use |
| **Age Restrictions** | PP-18 years of age and older (initial therapy) |
| **Prescriber Restrictions** | PP-Prescribed by or in consultation with a dermatologist (initial therapy), PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD-presc/consult-gastro |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | PP-Initial Therapy-The patient meets ONE of the following conditions (a or b): a) The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant. NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g., an adalimumab product [Humira], a certolizumab pegol product [Cimzia], an etanercept product [Enbrel, Erelzi], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Stelara [ustekinumab SC injection], Taltz [ixekizumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional systemic agent for psoriasis)b) The patient has a |

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

# SOLARAZE

## Products Affected

- diclofenac sodium topical gel 3 %

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

# SOMAVERT

## Products Affected

- Somavert

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

# SORAFENIB

## Products Affected

- sorafenib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Bone cancer, approve if the patient has recurrent chordoma or has osteosarcoma and has tried one standard chemotherapy regimen. GIST, approve if the patient has tried TWO of the following: imatinib mesylate, avapritinib, sunitinib, dasatinib, ripretinib or regorafenib. Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test and the medication is used in combination with azacitidine or decitabine or patient has had an allogeneic stem cell transplant and is in remission. Renal cell carcinoma (RCC)-approve if the patient has relapsed or advanced clear cell histology and the patient has tried at least one systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and sorafenib is used in combination with topotecan. HCC-approve if the patient has unresectable or metastatic disease. Soft tissue sarcoma-approve if the patient has angiosarcoma or desmoid tumors (aggressive fibromatosis) or solitary fibrous |

| PA Criteria | Criteria Details |
|---|---|
| | tumor/hemangiopericytoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. Please note for all diagnoses: Part B before Part D Step Therapy applies only to beneficiaries enrolled in an MA-PD plan |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Bone cancer, Soft tissue sarcoma, gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, ovarian, fallopian tube, primary peritoneal cancer, myeloid/lymphoid neoplasms with eosinophilia |
| **Part B Prerequisite** | Yes |

# SPRAVATO

## Products Affected

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

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

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

# SPRYCEL

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis for which Sprycel is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For melanoma, cutaneous- KIT mutation and previous therapies. |
| **Age Restrictions** | GIST/chondrocarcoma or chordoma/ melanoma, cutaneous-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | For CML, patient must have Ph-positive CML. For ALL, patient must have Ph-positive ALL. GIST - approve if the patient has tried imatinib or avapritinib. For melanoma, cutaneous - approve if patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | GIST, chondrosarcoma, chordoma, melanoma cutaneous |
| **Part B Prerequisite** | No |

# STELARA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | PP-6 years and older (initial therapy). |
| **Prescriber Restrictions** | Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy). |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | PP initial - Approve Stelara SC if the patient has tried one traditional systemic agent for psoriasis for at least 3 months unless intolerant or if the patient has a contraindication to methotrexate. Note: Examples of traditional systemic agents used for psoriasis include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. CD, induction therapy - approve single dose of IV formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumb, infliximab) OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas |

| PA Criteria | Criteria Details |
|---|---|
| | OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). CD, initial therapy subcutaneous (only after receiving single IV loading dose within 2 months of initiating therapy with Stelara SC) - approve the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one conventional systemic therapy for CD OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence).UC, induction therapy, approve if the patient has tried one systemic agent for ulcerative colitis or if the patient has pouchitis and has tried an antibiotic, probiotic, corticosteroid enema or mesalamine enema. UC, initial therapy subcutaneous-before the SC formulation can be approved the patient must have received a single IV loading dose within 2 months of initiating therapy with Stelara SC and try one systemic agent for ulcerative colitis or if the patient has pouchitis and has tried an antibiotic, probiotic, corticosteroid enema or mesalamine enema. PP/PsA/CD/UC cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# STIVARGA

## Products Affected

- Stivarga

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status. |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For GIST, patient must have previously been treated with imatinib or Ayvakit and sunitinib or Sprycel. For HCC, patient must have previously been treated with at least one systemic regimen. Soft tissue sarcoma, advanced or metastatic disease-approve if the patient has non-adipocytic sarcoma, angiosarcoma, or pleomorphic rhabdomyosarcoma. Osteosarcoma-approve if the patient has relapsed/refractory or metastatic disease and the patient has tried one systemic chemotherapy regimen. Colon and Rectal cancer/Appendiceal cancer-approve if the patient has advanced or metastatic disease, has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient meets one of the following (i or ii): i. patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type), the patient has tried Erbitux or Vectibix or the patient's tumor did not originate on the left side of the colon (from the splenic fixture to rectum) or ii. the patient's tumor or metastases has a RAS mutation (either KRAS mutation or NRAS mutation). Glioblastoma-approve if the patient has recurrent disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | Soft tissue Sarcoma, Osteosarcoma, Glioblastoma, Appendiceal cancer |
| **Part B Prerequisite** | No |

# STRENSIQ

## Products Affected

- Strensiq

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic and lab test results |
| **Age Restrictions** | Disease onset-less than or equal to 18 |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of hypophosphatasia or related disorders. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Hypophosphatasia - Perinatal/Infantile- and Juvenile-Onset-Patient must meet both A and B for approval. A) Diagnosis is supported by one of the following (i, ii, or iii): i. Molecular genetic testing documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation OR ii. Low baseline serum alkaline phosphatase activity OR iii. An elevated level of a tissue non-specific alkaline phosphatase substrate (i.e., serum pyridoxal 5'-phosphate, serum or urinary inorganic pyrophosphate, urinary phosphoethanolamine) AND B) Patient meets one of the following (i or ii): i. Patient currently has, or has a history of clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, premature tooth loss, muscle weakness, poor feeding, failure to thrive, respiratory problems, Vitamin B6-dependent seizures) OR ii. Patient has a family history (parent or sibling) of hypophosphatasia without current clinical manifestations of hypophosphatasia |
| **Indications** | All FDA-approved Indications. |

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

# SUCRAID

## Products Affected

- Sucraid

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic and lab test results (as specified in the Other Criteria field) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient meets the following criteria (A and B): A) The diagnosis is established by one of the following (i or ii): i. Patient has endoscopic biopsy of the small bowel with disaccharidase levels consistent with congenital sucrose-isomaltase deficiency as evidenced by ALL of the following (a, b, c, and d): a) Decreased (usually absent) sucrase (normal reference: greater than 25 U/g protein), b) Decreased to normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein], c) Decreased maltase (normal reference: greater than 100 U/g protein), d) Decreased to normal lactase (normal reference: greater than 15 U/g protein) OR ii. Patient has a molecular genetic test demonstrating homozygous or compound heterozygous pathogenic or likely pathogenic sucrase-isomaltase gene variant AND B) Patient has symptomatic congenital sucrose-isomaltase deficiency (e.g., diarrhea, bloating, abdominal cramping). |
| **Indications** | All FDA-approved Indications. |

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

# SUNITINIB

## Products Affected

- sunitinib malate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Gastrointestinal stromal tumors (GIST), approve if the patient has tried imatinib or Ayvakit or if the patient has succinate dehydrogenase (SDH)-deficient GIST. Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried at least one systemic chemotherapy. Renal Cell Carcinoma (RCC), clear cell or non-clear cell histology-approve if the patient is at high risk of recurrent clear cell RCC following nephrectomy and Sutent is used for adjuvant therapy or if the patient has relapsed or advanced disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease. Pheochromocytoma/paraganglioma-approve if the patient has unresectable or metastatic disease. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and Hurthle) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma, pheochromocytoma/paraganglioma, myeloid/lymphoid neoplasms with eosinophilia, GIST-unresectable succinate dehydrogenase (SDH)-deficient GIST, or use after avapritinib. |
| **Part B Prerequisite** | No |

# SYMDEKO

## Products Affected

- Symdeko

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Patients with unknown CFTR gene mutations, Combination therapy with Orkambi, Kalydeco or Trikafta |
| **Required Medical Information** | Diagnosis, specific CFTR gene mutations |
| **Age Restrictions** | Six years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF |
| **Coverage Duration** | 1 year |
| **Other Criteria** | CF - must be homozygous for the F508del mutation or have at least one mutation in the CFTR gene that is responsive to the requested medication. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SYMLIN

## Products Affected

- SymlinPen 120
- SymlinPen 60

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

# TABRECTA

## Products Affected

- Tabrecta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has advanced or metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping or high-level MET amplification, as detected by an approved test. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Non-small cell lung cancer with high-level MET amplification. |
| **Part B Prerequisite** | No |

# TAFAMIDIS

## Products Affected

- Vyndamax

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

# TAFINLAR

## Products Affected

- Tafinlar oral capsule
- Tafinlar oral tablet for suspension

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis for which Tafinlar is being used. BRAF V600 mutations |
| **Age Restrictions** | 1 year and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC, must have BRAF V600E mutation. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation postive disease and the medication will be taken in combination with Mekinist. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c, or d): a) |

| PA Criteria | Criteria Details |
|---|---|
| | glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma OR d)Oligodendroglioma OR iii. Melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR patient has Erdheim Chester disease AND patient has BRAF V600-mutation positive disease. Metastatic or solid tumors-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets) AND patient has no satisfactory alternative treatment options. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer-approve if the patient meets the following (A, B, and C): A) Patient has recurrent disease, AND B) Patient has BRAF V600 mutation-positive disease, AND C) The medication will be taken in combination with Mekinist (trametinib tablets). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Patients with Differentiated Thyroid Cancer,  Biliary tract cancer, central nervous system cancer, histiocytic neoplasm, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer |
| **Part B Prerequisite** | No |

# TAGRISSO

## Products Affected

- Tagrisso

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NSCLC-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)- approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note-examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC-Post resection-approve if the patient has completely resected disease and has received previous adjuvant chemotherapy or if the patient is inegligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# TALTZ

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) |
| **Required Medical Information** | Diagnosis, Previous medication use |
| **Age Restrictions** | PP-6 years and older (initial therapy), all other dx-18 years of age and older (initial therapy) |
| **Prescriber Restrictions** | All dx initial therapy only-PP-Prescribed by or in consultation with a dermatologist. PsA prescribed by or in consultation with a rheumatologist or a dermatologist. AS/spondylo -prescribed by or in consultation with a rheum. |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | Initial Therapy - Plaque Psoriasis-approve if the patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant OR the patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic. PsA Initial-Approve. AS initial-approve. Non-Radiographic Axial Spondyloarthritis-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or sacroiliitis reported on magnetic resonance imaging. Continuation Therapy - approve if the patient has responded, as determined by the prescriber. |
| **Indications** | All FDA-approved Indications. |

| 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

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and melanoma, cutaneous, prior therapies tried. For melanoma, cutaneous, KIT mutation status. |
| **Age Restrictions** | ALL/GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | Patients new to therapy with Acute lymphoblastic leukemia, philadelphia chromosome positive or chronic myeloid leukemia- approve if the patient has tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafinib or ripretinib. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement. Pigmented villonodular synovitis/tenosynovial giant cell tumor-approve if the patient has tried Turalio or cannot take Turalio, according to the prescriber. For melanoma, cutaneous - approve if the patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST), Pigmented villonodular synovitis/tenosynovial giant cell tumor, Myeloid/Lymphoid neoplasms with Eosinophilia, melanoma cutaneous. |
| **Part B Prerequisite** | No |

# TAZAROTENE

## Products Affected

- tazarotene topical cream
- tazarotene topical gel

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

# TAZVERIK

## Products Affected

- Tazverik

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Epitheliod Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if the patient has relapsed or refractory disease and there are no appropriate alternative therapies or the patient has tried at least two prior systemic therapies. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TECVAYLI

## Products Affected

- Tecvayli

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

# TEPMETKO

## Products Affected

- Tepmetko

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NSCLC-approve if the patient has advanced or metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutations or patient has high-level MET amplification, as detected by an approved test. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Non-small cell lung cancer with high-level MET amplification. |
| **Part B Prerequisite** | No |

# TERIPARATIDE

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with other medications for osteoporosis |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/lifetime. |
| **Other Criteria** | Treatment of PMO, approve if pt has tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR pt has severe renal impairment (creatinine clearance less than 35 mL/min) or CKD or pt has had an osteoporotic fracture or fragility fracture. Increase bone mass in men (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) with primary or hypogondal osteoporosis/Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, |

| PA Criteria | Criteria Details |
|---|---|
| | esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture. Patients who have already taken teriparatide for 2 years - approve if the patient is at high risk for fracture. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TETRABENAZINE

## Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism. |
| **Part B Prerequisite** | No |

# THALOMID

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | MM, myelofibrosis-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Myelofibrosis, approve if according to the prescriber the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/mL or if the patient has serum erythropoietin level less than 500 mU/mL and experienced no response or loss of response to erythropoietic stimulating agents. Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease. Castleman's disease-approve if the patient |

| PA Criteria | Criteria Details |
|---|---|
| | has multicentric Castleman's disease, and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi's Sarcoma, Castleman's Disease. |
| **Part B Prerequisite** | No |

# TIBSOVO

## Products Affected

- Tibsovo

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

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | Yes |

# TIVDAK

## Products Affected

- Tivdak

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

# TOBRAMYCIN (NEBULIZATION)

## Products Affected

- tobramycin in 0.225 % NaCl
- tobramycin inhalation

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

# TOLVAPTAN

## Products Affected

- tolvaptan

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Jynarque. |
| **Required Medical Information** | Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion). |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 30 days |
| **Other Criteria** | Hyponatremia - Pt must meet ONE of the following:  1. serum sodium less than 125 mEq/L at baseline, OR 2.  marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on tolvaptan and has received less than 30 days of therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TOPICAL AGENTS FOR ATOPIC DERMATITIS

## Products Affected

- pimecrolimus
- tacrolimus topical

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

# TOPICAL RETINOID PRODUCTS

## Products Affected

- tretinoin topical

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

# TOPIRAMATE/ZONISAMIDE

## Products Affected

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

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

# TRANSDERMAL FENTANYL

## Products Affected

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

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

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

# TRANSMUCOSAL FENTANYL DRUGS

## Products Affected

- fentanyl citrate buccal lozenge on a handle

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer pain (ie, FDA labeled use) prior to reviewing for quantity exception. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TRELSTAR

## Products Affected

- Trelstar intramuscular suspension for reconstitution

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

# TRIENTINE

## Products Affected

- trientine oral capsule 250 mg

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

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

# TRIKAFTA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko. |
| **Required Medical Information** | Diagnosis, specific CFTR gene mutations, concurrent medications |
| **Age Restrictions** | 2 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF |
| **Coverage Duration** | 1 year |
| **Other Criteria** | CF - must have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TRODELVY

## Products Affected

- Trodelvy

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

# TRUQAP

## Products Affected

- Truqap

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Breast Cancer-Approve if the patient meets the following (A, B, C, D and E): A) Patient has locally advanced or metastatic disease, AND B) Patient has hormone receptor positive (HR+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has at least one phosphatidylinositol 3-kinase (PIK3CA), serine/threonine protein kinase (AKT1), or phosphatase and tensin homolog (PTEN)-alteration, AND E) Patient meets one of the following (i or ii): i. Patient has had progression with at least one endocrine-based regimen in the metastatic setting (Note:  Examples of endocrine therapy include anastrozole, exemestane, and letrozole.) OR ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TUKYSA

## Products Affected

- Tukysa oral tablet 150 mg, 50 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Breast Cancer-approve if the patient has recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-positive disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TURALIO

## Products Affected

- Turalio oral capsule 125 mg

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

# UBRELVY

## Products Affected

- Ubrelvy

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

# UPTRAVI

## Products Affected

- Uptravi oral

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension. |
| **Required Medical Information** | Confirmation of right heart catheterization, medication history (as described in Other Criteria) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VALCHLOR

## Products Affected

- Valchlor

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Cutaneous lymphoma-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has chronic/smoldering subtype of adult T-cell leukemia/lymphoma. Langerhans cell histiocytosis-approve if the patient has unifocal Langerhans cell histiocytosis with isolated skin disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Adults with T-cell leukemia/lymphoma, Langerhans Cell Histiocytosis |
| **Part B Prerequisite** | No |

# VALTOCO

## Products Affected

- Valtoco

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

# VANCOMYCIN

## Products Affected

- vancomycin oral capsule 125 mg, 250 mg

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

# VANFLYTA

## Products Affected

- Vanflyta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Acute Myeloid Leukemia: approve if the patient has FLT3-ITD mutation-positive disease as detected by an approved test and this medication is being used for induction, 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 |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | AML-approve if used in combination with azacitidine, decitabine, or cytarabine. CLL/SLL- approve. Mantle Cell Lymphoma- approve if the patient has tried at least one systemic regimen. Multiple Myeloma- approve if the patient has t (11,14) translocation AND has tried at least one systemic regimen for multiple myeloma AND Venclexta will be used in combination with dexamethasone. Systemic light chain amyloidosis-approve if the patient has t (11, 14) translocation and has tried at least one systemic regimen. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Mantle Cell Lymphoma, waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, multiple myeloma, systemic light chain amyloidosis |
| **Part B Prerequisite** | No |

# VERZENIO

## Products Affected

- Verzenio

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1year |
| **Other Criteria** | Breast Cancer, Early-Approve if pt meets (A,B,C and D): A)Pt has HR+disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt has node-positive disease at high risk of recurrence AND D)Pt meets ONE of the following (i or ii): i.Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one of the following (a,b, or c): a)Pt is a postmenopausal woman, OR b)Pt is a pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, OR 2-Pt has had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is a man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets one of the following (a or b): a)Pt is a postmenopausal woman or man OR b)Pt is a pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Patient has had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Recurrent or Metastatic in Women-Approve if pt meets (A, B, C and D): A) Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i or ii): i.Pt is a |

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

# VIGABATRIN

## Products Affected

- vigabatrin
- Vigadrone
- Vigpoder

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

# VIMIZIM

## Products Affected

- Vimizim

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

# VISTOGARD

## Products Affected

- Vistogard

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

# VITRAKVI

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, NTRK gene fusion status |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Solid tumors - approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VIZIMPRO

## Products Affected

- Vizimpro

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, EGFR status, exon deletions or substitutions |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NSCLC-approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VONJO

## Products Affected

- Vonjo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Myelofibrosis (MF), including primary MF, post-polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient meets either (A, B, or C): (A) the patient has a platelet count of less than 50 X 109 /L (less than 50,000/mcL) and meets one of the following criteria (a or b):a) Patient has intermediate-risk or high-risk disease and is not a candidate for transplant, or b) Patient has lower-risk disease OR (B) Patient has a platelet count of greater than or equal to 50 X 109 /L (greater than or equal to 50,000/mcL) and meets all of the following criteria (a, b and c): a) Patient has high-risk disease, AND b) Patient is not a candidate for transplant, AND c) Patient has tried Jakafi (ruxolitinib tablets) or Inrebic (fedratinib capsules) OR (C) patient has myelofibrosis-associated anemia with symptomatic splenomegaly and/or constitutional symptoms. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VORICONAZOLE (ORAL)

## Products Affected

- voriconazole

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

# VOSEVI

## Products Affected

- Vosevi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Genotype, prescriber specialty, other medications tried or used in combination with requested medication |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| **Coverage Duration** | Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug |
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Indications consistent with current AASLD/IDSA guidance |
| **Part B Prerequisite** | No |

# VOTRIENT

## Products Affected

- pazopanib
- Votrient

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Soft tissue sarcoma other than GIST-approve if the patient has advanced or metastatic disease and has ONE of the following: alveolar soft part sarcoma, angiosarcoma, desmoid tumors (aggressive fibromatosis, dermatofibrosarcoma protuberans with fibrosarcomatous transformation, non-adipocytic sarcoma or pleomorphic rhabdomyosarcoma. Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has recurrent or metastatic disease. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or advanced disease or VonHippel-Lindau disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has succinate dehydrogenase (SDH)-deficient GIST OR the patient has tried TWO of the following: Gleevec, Ayvakit, Sutent, Sprycel, Qinlock or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried at least one systemic therapy. Bone cancer-approve if the patient has chondrosarcoma and has metastatic widespread disease. |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma, bone cancer. |
| **Part B Prerequisite** | No |

# VUMERITY

## Products Affected

- Vumerity

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

# WELIREG

## Products Affected

- Welireg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Renal Cell Carcinoma- approve if pt has advanced disease AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND has tried at least one a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). [Note: Examples of PD-1 inhibitor or PD-L1 inhibitor include: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Bavencio (avelumab intravenous infusion). Examples of VEGF-TKI include Cabometyx (cabozantinib tablets), Lenvima (lenvatinib capsules), Inlyta (axitinib tablets), Fotivda (tivozanib capsules), pazopanib, sunitinib, and sorafenib.] Van Hippel-Lindau Disease-approve if the patient meets the following (A, B, and C): A) Patient has a von Hippel-Lindau (VHL) germline alteration as detected by genetic testing, B) Does not require immediate surgery and C) Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv): i. Central nervous system hemangioblastomas, OR ii. Pancreatic neuroendocrine tumors, OR iii. Renal cell carcinoma, OR iv. Retinal hemangioblastoma. |
| **Indications** | All FDA-approved Indications. |

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

# XALKORI

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Anaplastic large cell lymphoma/IMT-patients greater than or equal to 1 year of age. All other diagnoses-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test and patients new to therapy must have a trial of Alecensa prior to approval of Xalkori. Metastatic non-small cell lung cancer, approve if the patient has ROS1 rearrangement positive disease, as detected by an approved test. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has received at least one prior systemic treatment. Histiocytic neoplasm-approve if the patient has ALK rearrangement/fusion-positive disease and meets one of the following criteria (i, ii, or iii): (i. Patient has Langerhans cell histiocytosis, OR ii. Patient has Erdheim-Chester disease OR iii. Patient has Rosai-Dorfman disease. NSCLC with MET mutation-approve if the patient has high level MET amplification or MET exon 14 skipping mutation. Inflammatory Myofibroblastic Tumor-approve if the patient has ALK positive disease and the patient has advanced, recurrent or metastatic disease or the tumor is |

| PA Criteria | Criteria Details |
|---|---|
| | inoperable. Melanoma, cutaneous-approve if the patient has ALK fusion disease or ROS1 fusion disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous. |
| **Part B Prerequisite** | No |

# XDEMVY

## Products Affected

- Xdemvy

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

# XELJANZ

## Products Affected

- Xeljanz oral solution
- Xeljanz oral tablet
- Xeljanz XR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with a biologic or with a Targeted Synthetic DMARD for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil]. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | AS/PsA/RA/UC-18 years and older (initial therapy) |
| **Prescriber Restrictions** | RA, JIA/JRA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | Approve through 12/31/24 |
| **Other Criteria** | RA initial-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. PsA initial, approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial and the requested medication will be used in combination with methotrexate or another conventional synthetic disease modifying antirheumatic drug (DMARD), unless contraindicated. UC-Approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis or was unable to tolerate a 3-month trial. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis]- |

| PA Criteria | Criteria Details |
|---|---|
| | initial-approve Xeljanz immediate release tablets or solution if the patient meets the following: patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AS-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XERMELO

## Products Affected

- Xermelo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, previous therapy, concomitant therapy |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Initial therapy - approve if the patient meets ALL of the following criteria: 1) patient has been on long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]) AND 2) while on long-acting SSA therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day, AND 3) Xermelo will be used concomitantly with a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with a long-acting SSA therapy for carcinoid syndrome diarrhea. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XIAFLEX

## Products Affected

- Xiaflex

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Retreatment for Peyronie's Disease (i.e., treatment beyond eight injections). |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Dupuytren's Contracture-administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture. Peyronie's Disease -administered by a healthcare provider experienced in the treatment of male urological diseases. |
| **Coverage Duration** | Dupuytren's Contracture-3 months, Peyronie's Disease-6 months |
| **Other Criteria** | Dupuytren's Contracture-at baseline (prior to initial injection of Xiaflex), the patient had contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint of at least 20 degrees AND the patient will not be treated with more than a total of three injections (maximum) per affected cord as part of the current treatment course. Peyronie's Disease-the patient meets ONE of the following (i or ii): i. at baseline (prior to use of Xiaflex), the patient has a penile curvature deformity of at least 30 degrees OR in a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees AND the patient has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# XOLAIR

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another monoclonal antibody therapy. |
| **Required Medical Information** | Moderate to severe persistent asthma baseline (defined as prior to receiving any treatment with Xolair or another monoclonal antibody that may lower IgE levels) IgE level of at least 30 IU/mL. For asthma, patient has a baseline (baseline is defined as prior to receiving any Xolair or another monoclonal antibody that may interfere with allergen testing) positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay (eg, immunoCAP, ELISA) or the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). CIU - must have urticaria for more than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine). |
| **Age Restrictions** | Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years and older. Food Allergy-1 yr and older |
| **Prescriber Restrictions** | Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist. Polyps-prescribed by or in consult with an allergist, immunologist, or otolaryngologist. Food allergy- allergist or immunologist |
| **Coverage Duration** | asthma/CIU-Initial tx 4 months, Polyps-initial-6 months, continued tx 12 months, Food allergy-1 yr |
| **Other Criteria** | Moderate to severe persistent asthma approve if pt meets criteria 1 and 2: 1) pt has received at least 3 months of combination therapy with an inhaled |

| PA Criteria | Criteria Details |
|---|---|
| | corticosteroid and at least one additional asthma controller or asthma maintenance medication (Examples: LABA, LAMA, leukotriene receptor antagonist, monoclonal antibody therapies for asthma) and 2)patient's asthma is uncontrolled or was uncontrolled prior to receiving Xolair or another monoclonal antibody therapy for asthma as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring hospitalization, urgent care visit or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For CIU cont tx - have responded to therapy as determined by the prescribing physician. Nasal Polyps Initial-Approve if the patient has a baseline (defined as prior to receiving any treatment with Xolair or another monoclonal antibody therapy that may lower IgE) IgE level greater than or equal to 30 IU/ml, patient is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell and patient is currently receiving therapy with an intranasal corticosteroid. Nasal polyps continuation-approve if the patient continues to receive therapy with an intranasal corticosteroid and has responded to therapy. IgE-Mediated Food Allergy-approve if pt meets (A, B, C and D): (A) baseline IgE greater than or equal to 30 IU/mL, and (B) positive skin prick test to one or more foods and positive in vitro test for IgE to one or more foods, and (C) history of allergic reaction that met all of the following: pt demonstrated signs and symptoms of a significant systemic allergic reaction, and reaction occurred within a short period of time following a known ingestion of the food, and prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector, and (D) pt has been prescribed an epinephrine auto-injector. |
| **Indications** | All FDA-approved Indications. |

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

# XOSPATA

## Products Affected

- Xospata

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, FLT3-mutation status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | AML - approve if the patient has relapsed or refractory disease AND the disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Lymphoid, Myeloid Neoplasms |
| **Part B Prerequisite** | No |

# XPOVIO

## Products Affected

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

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

| PA Criteria | Criteria Details |
|---|---|
| | includes patients with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma)-approve if the patient has been treated with at least two prior systemic therapies. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Treatment of multiple myeloma in combination with daratumumb or pomalidomide |
| **Part B Prerequisite** | No |

# XTANDI

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis for which Xtandi is being used. |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Prostate cancer-castration-resistant [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) agonist or the medication is concurrently used with Firmagon or if the patient has had a bilateral orchiectomy. Prostate cancer- Non-Metastatic, Castration-Sensitive - approve if pt has biochemical recurrence and is at high risk for metastasis. [Note: High-risk biochemical recurrence is defined as prostate-specific antigen (PSA) doubling time less than or equal to 9 months.] |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XYREM

## Products Affected

- sodium oxybate

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

# ZARXIO

## Products Affected

- Zarxio

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation.SCN - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. |
| **Coverage Duration** | chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT- 3 mo.Other=12mo. Radi-1 mo. |
| **Other Criteria** | Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgramstim products, pegfilgrastim products) and a reduced dose or |

| PA Criteria | Criteria Details |
|---|---|
| | frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Acute lymphocytic leukemia (ALL). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome) |
| **Part B Prerequisite** | No |

# ZEJULA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after platinum-based chemotherapy regimen and if the patient is in complete or partial response to first-line primary treatment or if the patient has recurrent disease and a BRCA mutation. Uterine leiomyosarcoma-approve if the patient has BRCA2 mutation and has tried one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Uterine Leiomyosarcoma |
| **Part B Prerequisite** | No |

# ZELBORAF

## Products Affected

- Zelboraf

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | BRAFV600 mutation status required. |
| **Age Restrictions** | All diagnoses (except CNS cancer)-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. HCL - must have tried at least one other systemic therapy for hairy cell leukemia OR is unable to tolerate purine analogs and Zelboraf will be used in combination with Gazyva (obinutuzumab intravenous infusion) as initial therapy. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. Erdheim-Chester disease, in patients with BRAF V600 mutation-approve. Central Nervous System Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a or b): a) glioma OR b) Glioblastoma OR iii. Melanoma with brain metastases AND the medication with be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. |

| PA Criteria | Criteria Details |
|---|---|
| | Multisystem disease OR ii. Pulmonary disease OR iii. Central nervous system lesions AND the patient has BRAF V600-mutation positive disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or Hurthle cell) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm |
| **Part B Prerequisite** | No |

# ZEPOSIA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | MS-Concurrent use with other disease-modifying agents used for multiple sclerosis.UC- Concurrent Use with a Biologic or with a Targeted Synthetic Disease-modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | UC-18 years and older |
| **Prescriber Restrictions** | MS-Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. UC-Prescribed by or in consultation with a gastroenterologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | MS-approve. Ulcerative Colitis, initial-approve if the patient has tried a preferred adalimumab product. Note-a trial of Simponi SC, a non-preferred adalimumab product or infliximab would also count). Cont tx-approve if the patient has been established on Zeposia. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Hyrimoz (NDCs starting with -61314), adalimumab-adaz, adalimumab-adbm. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZEPZELCA

## Products Affected

- Zepzelca

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

# ZIEXTENZO

## Products Affected

- Ziextenzo

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

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

# 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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Previous treatment with Zurzuvae during the current episode of postpartum depression |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist |
| **Coverage Duration** | 14 days |
| **Other Criteria** | Postpartum depression-approve if the patient meets the following (A, B and C): A.Patient meets BOTH of the following (i and ii): i. Patient has been diagnosed with severe depression, AND ii. Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery, AND B. Patient is less than or equal to 12 months postpartum, AND C. Patient is not currently pregnant. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZYDELIG

## Products Affected

- Zydelig

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | CLL/SLL-approve if the patient has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | small lymphocytic lymphoma |
| **Part B Prerequisite** | No |

# ZYKADIA

## Products Affected

- Zykadia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Erdheim-Chester Disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. NSCLC, ALK positive-approve if the patient has advanced or metastatic disease that is ALK positive as detected by an approved test and for patients new to therapy must have a trial of Alecensa prior to approval of Zykadia. NSCLC, ROS1 Rearrangement-approve if the patient has advanced or metastatic disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement. Erdheim-Chester disease. |
| **Part B Prerequisite** | No |

# ZYNLONTA

## Products Affected

- Zynlonta

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

# ZYNYZ

## Products Affected

- Zynyz

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

# ZYTIGA

## Products Affected

- abiraterone oral tablet 250 mg, 500 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Prostate Cancer-Metastatic, Castration-Resistant (mCRPC)-Approve if abiraterone is being used in combination with prednisone or dexamethasone and the medication is used concurrently used with a gonadotropin-releasing hormone (GnRH) agonist, or the medication is concurrently used with Firmagon or the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration-sensitive (mCSPC)-approve if the medication is used in combination with prednisone and the medication is concurrently used with a gonadotropin-releasing hormone agonist or concurrently used with Firmagon or the patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the patient meets all of the following criteria (A, B, and C): A) abiraterone is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i, ii or iii): i. abiraterone with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) agonist OR ii. Patient has had a bilateral orchiectomy OR iii. the medication is used in combination with Firmagon. Prostate cancer-very-high-risk-group-approve if according to the prescriber the patient is in the very-high-risk group, the |

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

EmblemHealth®

# PART B VERSUS PART D

## Products Affected

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

- everolimus (immunosuppressive)
- floxuridine
- fludarabine
- fluorouracil intravenous
- Folotyn
- formoterol fumarate
- fulvestrant
- ganciclovir sodium
- Gazyva
- gemcitabine intravenous recon soln
- gemcitabine intravenous solution 1 gram/26.3 mL (38 mg/mL), 2 gram/52.6 mL (38 mg/mL), 200 mg/5.26 mL (38 mg/mL)
- gemcitabine intravenous solution 100 mg/mL
- Gengraf
- granisetron HCl oral
- Halaven
- Heplisav-B (PF)
- Hizentra
- idarubicin
- ifosfamide
- Imfinzi
- Intralipid intravenous emulsion 20 %
- ipratropium bromide inhalation
- ipratropium-albuterol
- irinotecan
- Istodax
- Ixempra
- Jevtana
- Jynneos (PF)
- Khapzory intravenous recon soln 175 mg
- Kyprolis
- levalbuterol HCl
- levoleucovorin calcium
- Lioresal
- melphalan HCl
- mesna
- methotrexate sodium
- methotrexate sodium (PF)
- methylprednisolone oral tablet
- milrinone
- milrinone in 5 % dextrose
- mitomycin intravenous
- mitoxantrone
- Mozobil
- mycophenolate mofetil
- mycophenolate mofetil (HCl)
- mycophenolate sodium
- Mylotarg
- nelarabine
- nitroglycerin in 5 % dextrose intravenous solution 100 mg/250 mL (400 mcg/mL), 25 mg/250 mL (100 mcg/mL), 50 mg/250 mL (200 mcg/mL)
- nitroglycerin intravenous
- Nulojix
- Oncaspar
- ondansetron
- ondansetron HCl oral solution
- ondansetron HCl oral tablet 4 mg, 8 mg
- Onivyde
- oxaliplatin
- paclitaxel
- Paraplatin
- pemetrexed disodium intravenous recon soln
- pentamidine inhalation
- Perjeta
- Plenamine
- plerixafor
- Portrazza
- Prehevbrio (PF)
- Premasol 10 %
- Prograf intravenous
- Prograf oral granules in packet
- Pulmozyme
- Recombivax HB (PF)
- romidepsin intravenous recon soln
- Sandimmune oral solution
- Simulect
- sirolimus
- sodium nitroprusside
- tacrolimus oral
- Tecentriq
- 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
- Xatmep
- Xgeva
- Yervoy
- Yondelis
- Zaltrap
- Zanosar
- Zirabev
- zoledronic acid intravenous solution
- zoledronic acid-mannitol-water intravenous piggyback 4 mg/100 mL

## Details

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

**Index**


**A**

Abelcet ..... 449
abiraterone oral tablet 250 mg, 500 mg . 447, 448
Abraxane ..... 449
acetylcysteine ..... 449
Actemra ACTPen ..... 3, 4
Actemra intravenous ..... 1, 2
Actemra subcutaneous ..... 3, 4
Actimmune ..... 449
acyclovir sodium intravenous solution ... 449
acyclovir topical ointment ..... 5
adalimumab-adaz ..... 6, 7
adalimumab-adbm subcutaneous pen injector kit ..... 6, 7
adalimumab-adbm subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL ..... 6, 7
adalimumab-adbm(CF) pen Crohns ..... 6, 7
adalimumab-adbm(CF) pen PS-UV ..... 6, 7
Adbry ..... 8
Adcetris ..... 449
Adempas ..... 9
Adstiladrin ..... 10
Aimovig Autoinjector ..... 11
Akeega ..... 12
albuterol sulfate inhalation solution for nebulization ..... 449
Aldurazyme ..... 13
Alecensa ..... 14, 15
Aliqopa ..... 449
alosetron ..... 16
Alunbrig oral tablet 180 mg, 30 mg, 90 mg ..... 18
Alunbrig oral tablets,dose pack ..... 18
Alyq ..... 281
Amabelz ..... 144, 145
ambrisentan ..... 40
amikacin injection solution 1,000 mg/4 mL, 500 mg/2 mL ..... 19, 20
amiodarone intravenous ..... 449
amphotericin B ..... 449
ampicillin sodium ..... 19, 20
ampicillin-sulbactam ..... 19, 20
APOKYN ..... 22
apomorphine ..... 22
aprepitant ..... 449
Arcalyst ..... 23
arformoterol ..... 449
Arikayce ..... 24, 25
armodafinil ..... 228
arsenic trioxide ..... 449
Asparlas ..... 26
Augtyro ..... 28
Avonex intramuscular pen injector kit ..... 29
Avonex intramuscular syringe kit ..... 29
Ayvakit ..... 30
azacitidine ..... 449
azathioprine oral tablet 50 mg ..... 449
azathioprine sodium ..... 449
azithromycin intravenous ..... 19, 20
aztreonam ..... 19, 20

**B**

Balversa ..... 31
Bavencio ..... 449
Belbuca ..... 208, 209
Beleodaq ..... 449
bendamustine intravenous recon soln ..... 449
Bendeka ..... 449
Benlysta ..... 32, 33
benztropine oral ..... 140
Besponsa ..... 449
Besremi ..... 34
Betaseron subcutaneous kit ..... 35
bexarotene ..... 36, 37
Bicillin C-R ..... 19, 20
Bicillin L-A ..... 19, 20

bleomycin ..... 449
Blincyto intravenous kit ..... 449
bortezomib injection recon soln 1 mg, 2.5 mg ..... 449
bortezomib injection recon soln 3.5 mg .. 449
bosentan ..... 40
Bosulif oral capsule 100 mg, 50 mg ..... 41
Bosulif oral tablet 100 mg, 400 mg, 500 mg ..... 41
Braftovi ..... 42
Briumvi ..... 43
Brukinsa ..... 44
budesonide inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL ..... 449
buprenorphine ..... 208, 209
busulfan ..... 449
Bydureon BCise ..... 128
Byetta subcutaneous pen injector 10 mcg/dose(250 mcg/mL) 2.4 mL, 5 mcg/dose (250 mcg/mL) 1.2 mL ..... 128

**C**

Cablivi injection kit ..... 46
Cabometyx ..... 47, 48
Calquence ..... 49, 50
Calquence (acalabrutinib mal) ..... 49, 50
Caprelsa oral tablet 100 mg, 300 mg ..... 51
carboplatin intravenous solution ..... 449
carglumic acid ..... 52
carmustine intravenous recon soln 100 mg ..... 449
Cayston ..... 53
cefoxitin ..... 19, 20
cefoxitin in dextrose (iso-osm) ..... 19, 20
ceftazidime ..... 19, 20
cefuroxime sodium injection recon soln 750 mg ..... 19, 20
cefuroxime sodium intravenous ..... 19, 20
Ceprotin (Blue Bar) ..... 54
Ceprotin (Green Bar) ..... 54
Chemet ..... 55
Chenodal ..... 56
Cholbam oral capsule 250 mg, 50 mg 57, 58
Cibinqo ..... 59, 60
cidofovir ..... 449
Cimerli ..... 61
Cimzia ..... 62, 63
Cimzia Powder for Reconst ..... 62, 63
Cimzia Starter Kit ..... 62, 63
cinacalcet ..... 64
Cinryze ..... 45
ciprofloxacin in 5 % dextrose ..... 19, 20
cisplatin intravenous solution ..... 449
cladribine ..... 449
clindamycin in 5 % dextrose ..... 19, 20
clindamycin phosphate injection ..... 19, 20
clindamycin phosphate intravenous .... 19, 20
Clinimix 5%/D15W Sulfite Free ..... 449
Clinimix 4.25%/D10W Sulfite Free ..... 449
Clinimix 4.25%/D5W Sulfite Free ..... 449
Clinimix 5%-D20W Sulfite Free ..... 449
Clinimix 6%-D5W (sulfite-free) ..... 449
Clinimix 8%-D10W(sulfite-free) ..... 449
Clinimix 8%-D14W(sulfite-free) ..... 449
clobazam oral suspension ..... 65
clobazam oral tablet ..... 65
clofarabine ..... 449
Clomid ..... 66
clomiphene citrate ..... 66
clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg ..... 138, 139
colistin (colistimethate Na) ..... 19, 20
Columvi ..... 67, 68
Cometriq oral capsule 100 mg/day(80 mg x1-20 mg x1), 140 mg/day(80 mg x1-20 mg x3), 60 mg/day (20 mg x 3/day) ..... 69
Copiktra ..... 70
Cosmegen ..... 449
Cotellic ..... 71, 72
Cresemba oral ..... 73
cromolyn inhalation ..... 449
Crysvita ..... 74, 75
cyclobenzaprine oral tablet 10 mg, 5 mg 141

cyclophosphamide intravenous recon soln ..... 449
cyclophosphamide oral capsule ..... 449
cyclophosphamide oral tablet ..... 449
cyclosporine intravenous ..... 449
cyclosporine modified..... 449
cyclosporine oral capsule..... 449
Cyltezo(CF) Pen..... 6, 7
Cyltezo(CF) Pen Crohn's-UC-HS..... 6, 7
Cyltezo(CF) Pen Psoriasis-UV ..... 6, 7
Cyltezo(CF) subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL ..... 6, 7
Cyramza..... 449
Cystagon ..... 77
Cystaran ..... 76
cytarabine..... 449
cytarabine (PF)..... 449
**D**
dacarbazine ..... 449
dactinomycin..... 449
dalfampridine ..... 78
Danyelza ..... 79
Darzalex..... 449
daunorubicin ..... 449
Daurismo oral tablet 100 mg, 25 mg ..... 80
decitabine..... 449
deferasirox..... 81
deferiprone ..... 82
deferoxamine..... 449
DermacinRx Lidocan..... 207
dexrazoxane HCl..... 449
Diacomit..... 83
diazepam injection ..... 138, 139
Diazepam Intensol ..... 138, 139
diazepam oral concentrate..... 138, 139
diazepam oral solution ..... 138, 139
diazepam oral tablet ..... 138, 139
diclofenac sodium topical gel 3 %..... 334
dimethyl fumarate oral capsule,delayed release(DR/EC) 120 mg, 120 mg (14)-240 mg (46), 240 mg..... 84
diphenhydramine HCl oral elixir ..... 142
dobutamine..... 449
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)..... 449
docetaxel ..... 449
dopamine in 5 % dextrose..... 449
dopamine intravenous solution 200 mg/5 mL (40 mg/mL), 400 mg/10 mL (40 mg/mL) ..... 449
Doptelet (10 tab pack)..... 85
Doptelet (15 tab pack)..... 85
Doptelet (30 tab pack)..... 85
Dotti ..... 144, 145
doxorubicin ..... 449
doxorubicin, peg-liposomal ..... 449
Doxy-100 ..... 19, 20
doxycycline hyclate intravenous..... 19, 20
dronabinol ..... 449
droxidopa ..... 86
Dupixent Pen subcutaneous pen injector 200 mg/1.14 mL, 300 mg/2 mL ..... 87, 88
Dupixent Syringe subcutaneous syringe 100 mg/0.67 mL, 200 mg/1.14 mL, 300 mg/2 mL ..... 87, 88
**E**
Elaprase..... 89
Eligard..... 130, 131
Eligard (3 month)..... 130, 131
Eligard (4 month)..... 130, 131
Eligard (6 month)..... 130, 131
Elrexfio ..... 90
Elzonris ..... 91
Emend oral suspension for reconstitution449
Emgality Pen..... 92, 93
Emgality Syringe subcutaneous syringe 120 mg/mL..... 92, 93
Empliciti..... 449
Enbrel Mini ..... 94, 95
Enbrel subcutaneous solution ..... 94, 95
Enbrel subcutaneous syringe..... 94, 95

Enbrel SureClick ..... 94, 95
Endari ..... 96
Engerix-B (PF) ..... 449
Engerix-B Pediatric (PF) ..... 449
Entyvio ..... 97, 98
Envarsus XR ..... 449
Epclusa oral pellets in packet 150-37.5 mg, 200-50 mg ..... 99
Epclusa oral tablet 200-50 mg, 400-100 mg ..... 99
Epidiolex ..... 100
epirubicin intravenous solution 200 mg/100 mL ..... 449
Epkinly ..... 101, 102
Eprontia ..... 381
Erbitux ..... 449
Erivedge ..... 105
Erleada oral tablet 240 mg, 60 mg ..... 106
erlotinib oral tablet 100 mg, 150 mg, 25 mg ..... 107, 108
ertapenem ..... 19, 20
Erwinase ..... 449
estradiol oral ..... 144, 145
estradiol transdermal patch semiweekly 144, 145
estradiol transdermal patch weekly. 144, 145
estradiol-norethindrone acet. ..... 144, 145
Etopophos ..... 449
etoposide intravenous ..... 449
everolimus (antineoplastic) oral tablet ... 109, 110
everolimus (antineoplastic) oral tablet for suspension 2 mg, 3 mg, 5 mg ..... 109, 110
everolimus (immunosuppressive) ..... 450
Exkivity ..... 111
Eylea ..... 112

**F**

Fabrazyme ..... 113
Fasenra ..... 114, 115
Fasenra Pen ..... 114, 115
fentanyl citrate buccal lozenge on a handle ..... 384
fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr ..... 382, 383
fingolimod ..... 116
Fintepla ..... 117
Firdapse ..... 118
Firmagon kit w diluent syringe ..... 119
floxuridine ..... 450
fluconazole in NaCl (iso-osm) ..... 21
fludarabine ..... 450
fluorouracil intravenous ..... 450
Folotyn ..... 450
formoterol fumarate ..... 450
Fotivda ..... 120
Fruzaqla oral capsule 1 mg, 5 mg ... 121, 122
fulvestrant ..... 450
Fyarro ..... 123
Fyavolv ..... 144, 145

**G**

gabapentin oral tablet extended release 24 hr 300 mg, 600 mg ..... 132
ganciclovir sodium ..... 450
Gattex 30-Vial ..... 124
Gattex One-Vial ..... 124
Gavreto ..... 125
Gazyva ..... 450
gefitinib ..... 169
gemcitabine intravenous recon soln ..... 450
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) ..... 450
gemcitabine intravenous solution 100 mg/mL ..... 450
Gengraf ..... 450
gentamicin in NaCl (iso-osm) intravenous piggyback 100 mg/100 mL, 60 mg/50 mL, 80 mg/100 mL, 80 mg/50 mL . 19, 20
gentamicin injection solution 40 mg/mL . 19, 20
gentamicin sulfate (ped) (PF) ..... 19, 20
Gilotrif ..... 126

glatiramer subcutaneous syringe 20 mg/mL, 40 mg/mL ..... 127
Glatopa subcutaneous syringe 20 mg/mL, 40 mg/mL ..... 127
Gralise oral tablet extended release 24 hr 300 mg, 450 mg, 600 mg, 750 mg, 900 mg ..... 132
granisetron HCl oral ..... 450
**H**
Halaven ..... 450
Harvoni oral pellets in packet 33.75-150 mg, 45-200 mg ..... 136
Harvoni oral tablet 45-200 mg, 90-400 mg ..... 136
Heplisav-B (PF) ..... 450
Hizentra ..... 450
Humira (PREFERRED NDCS STARTING WITH 00074) subcutaneous syringe kit 40 mg/0.8 mL ..... 146, 147
Humira Pen (PREFERRED NDCS STARTING WITH 00074) ..... 146, 147
Humira Pen Psor-Uveits-Adol HS (PREFERRED NDCS STARTING WITH 00074) ..... 146, 147
Humira(CF) (PREFERRED NDCS STARTING WITH 00074) subcutaneous syringe kit 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL ..... 146, 147
Humira(CF) Pedi Crohns Starter (PREFERRED NDCS STARTING WITH 00074) subcutaneous syringe kit 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL ..... 146, 147
Humira(CF) Pen (PREFERRED NDCS STARTING WITH 00074) subcutaneous pen injector kit 40 mg/0.4 mL, 80 mg/0.8 mL ..... 146, 147
Humira(CF) Pen Crohns-UC-HS (PREFERRED NDCS STARTING WITH 00074) ..... 146, 147
Humira(CF) Pen Pediatric UC (PREFERRED NDCS STARTING WITH 00074) ..... 146, 147
Humira(CF) Pen Psor-Uv-Adol HS (PREFERRED NDCS STARTING WITH 00074) ..... 146, 147
hydromorphone oral tablet extended release 24 hr ..... 208, 209
hydroxyzine HCl oral tablet ..... 142
Hyrimoz Pen Crohn's-UC Starter (Preferred NDCs starting with 61314) ..... 6, 7
Hyrimoz Pen Psoriasis Starter (Preferred NDCs starting with 61314) ..... 6, 7
Hyrimoz(CF) (Preferred NDCs starting with 61314) subcutaneous syringe 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL ..... 6, 7
Hyrimoz(CF) Pedi Crohn Starter (Preferred NDCs starting with 61314) subcutaneous syringe 80 mg/0.8 mL, 80 mg/0.8 mL- 40 mg/0.4 mL ..... 6, 7
Hyrimoz(CF) Pen (Preferred NDCs starting with 61314) ..... 6, 7
**I**
ibandronate intravenous ..... 38, 39
Ibrance ..... 148, 149
icatibant ..... 150, 151
Iclusig ..... 152
idarubicin ..... 450
Idhifa ..... 153
ifosfamide ..... 450
Ilaris (PF) ..... 154, 155
imatinib oral tablet 100 mg, 400 mg 156, 157
Imbruvica oral capsule 140 mg, 70 mg .. 158, 159
Imbruvica oral suspension ..... 158, 159
Imbruvica oral tablet 140 mg, 280 mg, 420 mg ..... 158, 159
Imfinzi ..... 450
imipenem-cilastatin ..... 19, 20
Imjudo ..... 160, 161
Ingrezza ..... 162
Ingrezza Initiation Pack ..... 162

Inlyta oral tablet 1 mg, 5 mg ..... 165
Inpefa oral tablet 200 mg, 400 mg ..... 166
Inqovi ..... 167
Inrebic ..... 168
Intralipid intravenous emulsion 20 % ..... 450
ipratropium bromide inhalation ..... 450
ipratropium-albuterol ..... 450
irinotecan ..... 450
Istodax ..... 450
ivermectin oral ..... 170
Iwilfin ..... 172
Ixempra ..... 450
**J**
Jakafi ..... 173, 174
Jaypirca oral tablet 100 mg, 50 mg ..... 175, 176
Jemperli ..... 177, 178
Jevtana ..... 450
Jinteli ..... 144, 145
Juxtapid ..... 179, 180
Jynneos (PF) ..... 450
**K**
Kadcyla ..... 181
Kalydeco ..... 182
Kanuma ..... 183
Kerendia ..... 184, 185
Kesimpta Pen ..... 186
Keytruda ..... 187
Khapzory intravenous recon soln 175 mg ..... 450
Kimmtrak ..... 188
Kisqali Femara Co-Pack oral tablet 200 mg/day(200 mg x 1)-2.5 mg, 400 mg/day(200 mg x 2)-2.5 mg, 600 mg/day(200 mg x 3)-2.5 mg ..... 189, 190
Kisqali oral tablet 200 mg/day (200 mg x 1), 400 mg/day (200 mg x 2), 600 mg/day (200 mg x 3) ..... 189, 190
Korlym ..... 191
Koselugo ..... 192, 193
Krazati ..... 194, 195
Kyprolis ..... 450
**L**
lapatinib ..... 198, 199
lenalidomide ..... 200, 201
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) ..... 202, 203
Leukine injection recon soln ..... 204
leuprolide subcutaneous kit ..... 130, 131
levalbuterol HCl ..... 450
levofloxacin in D5W ..... 19, 20
levofloxacin intravenous ..... 19, 20
levoleucovorin calcium ..... 450
Libtayo ..... 205, 206
lidocaine topical adhesive patch,medicated 5 % ..... 207
Lidocan III ..... 207
lincomycin ..... 19, 20
linezolid in dextrose 5% ..... 19, 20
linezolid-0.9% sodium chloride ..... 19, 20
Lioresal ..... 450
Lonsurf ..... 210
Loqtorzi ..... 211
lorazepam injection solution ..... 138, 139
lorazepam injection syringe 2 mg/mL ... 138, 139
Lorazepam Intensol ..... 138, 139
lorazepam oral concentrate ..... 138, 139
lorazepam oral tablet 0.5 mg, 1 mg, 2 mg ..... 138, 139
Lorbrena oral tablet 100 mg, 25 mg ..... 212
Lumakras ..... 213
Lumizyme ..... 214
Lunsumio ..... 215
Lupron Depot ..... 130, 131, 216
Lyllana ..... 144, 145
Lynparza ..... 217, 218
Lytgobi ..... 219
**M**
Margenza ..... 220

megestrol oral suspension 400 mg/10 mL (10 mL), 400 mg/10 mL (40 mg/mL), 625 mg/5 mL (125 mg/mL) ..... 221
megestrol oral tablet ..... 221
Mekinist oral recon soln ..... 222, 223
Mekinist oral tablet 0.5 mg, 2 mg ... 222, 223
Mektovi ..... 224
melphalan HCl ..... 450
memantine oral capsule,sprinkle,ER 24hr ..... 225
memantine oral solution ..... 225
memantine oral tablet ..... 225
Menest ..... 144, 145
Mepsevii ..... 226
meropenem intravenous recon soln 1 gram, 500 mg ..... 19, 20
mesna ..... 450
Methadone Intensol ..... 208, 209
methadone oral concentrate ..... 208, 209
methadone oral solution 10 mg/5 mL, 5 mg/5 mL ..... 208, 209
methadone oral tablet 10 mg, 5 mg. 208, 209
Methadose oral concentrate ..... 208, 209
methotrexate sodium ..... 450
methotrexate sodium (PF) ..... 450
methylergonovine oral ..... 227
methylprednisolone oral tablet ..... 450
Metro I.V. ..... 19, 20
metronidazole in NaCl (iso-osm) ..... 19, 20
metyrosine ..... 280
mifepristone oral tablet 300 mg ..... 191
milrinone ..... 450
milrinone in 5 % dextrose ..... 450
Mimvey ..... 144, 145
mitomycin intravenous ..... 450
mitoxantrone ..... 450
modafinil oral tablet 100 mg, 200 mg ..... 228
Monjuvi ..... 229
morphine oral tablet extended release .... 208, 209
Mounjaro ..... 128
moxifloxacin-sod.chloride(iso) ..... 19, 20
Mozobil ..... 450
Myalept ..... 230
mycophenolate mofetil ..... 450
mycophenolate mofetil (HCl) ..... 450
mycophenolate sodium ..... 450
Myfembree ..... 231, 232
Mylotarg ..... 450

**N**

nafcillin in dextrose (iso-osm) ..... 19, 20
nafcillin injection ..... 19, 20
Naglazyme ..... 233
Namzaric ..... 225
Nayzilam ..... 234
nelarabine ..... 450
Nerlynx ..... 235
Nexletol ..... 236, 237
Nexlizet ..... 238, 239
nilutamide ..... 240
Ninlaro ..... 241
nitisinone ..... 242
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) ..... 450
nitroglycerin intravenous ..... 450
Nivestym ..... 243, 244
norethindrone ac-eth estradiol oral tablet 0.5-2.5 mg-mcg, 1-5 mg-mcg ..... 144, 145
Nubeqa ..... 247
Nucala subcutaneous auto-injector . 248, 249
Nucala subcutaneous recon soln ..... 248, 249
Nucala subcutaneous syringe 100 mg/mL, 40 mg/0.4 mL ..... 248, 249
Nuedexta ..... 250
Nulojix ..... 450
Nuplazid ..... 251
Nurtec ODT ..... 252, 253
Nyvepria ..... 254, 255

**O**

Ocaliva ..... 256, 257
octreotide acetate ..... 258
Odomzo ..... 259

Ofev ..... 260, 261
Ojjaara ..... 262
Omnitrope ..... 133, 134, 135
Oncaspar ..... 450
ondansetron ..... 450
ondansetron HCl oral solution ..... 450
ondansetron HCl oral tablet 4 mg, 8 mg . 450
Onivyde ..... 450
Onureg ..... 263
Opdivo ..... 264
Opdualag ..... 265
Opsumit ..... 266
Orencia (with maltose) ..... 267, 268
Orencia ClickJect ..... 267, 268
Orencia subcutaneous syringe 125 mg/mL, 50 mg/0.4 mL, 87.5 mg/0.7 mL .. 267, 268
Orgovyx ..... 269
Orkambi oral granules in packet ..... 270
Orkambi oral tablet ..... 270
Orserdu oral tablet 345 mg, 86 mg ..... 271
Otezla ..... 272, 273
Otezla Starter oral tablets,dose pack 10 mg (4)-20 mg (4)-30 mg (47) ..... 272, 273
oxacillin in dextrose(iso-osm) ..... 19, 20
oxacillin injection ..... 19, 20
oxaliplatin ..... 450
Oxervate ..... 274
OxyContin oral tablet,oral only,ext.rel.12 hr 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg ..... 208, 209
Ozempic subcutaneous pen injector 0.25 mg or 0.5 mg (2 mg/3 mL), 1 mg/dose (4 mg/3 mL), 2 mg/dose (8 mg/3 mL) .... 128

**P**

paclitaxel ..... 450
Padcev ..... 275
Panretin ..... 276
Paraplatin ..... 450
pazopanib ..... 410, 411
Pemazyre ..... 277
pemetrexed disodium intravenous recon soln ..... 450
penicillamine oral tablet ..... 278
penicillin G pot in dextrose ..... 19, 20
penicillin G potassium ..... 19, 20
penicillin G sodium ..... 19, 20
pentamidine inhalation ..... 450
Perjeta ..... 450
Pfizerpen-G ..... 19, 20
phenobarbital ..... 143
pimecrolimus ..... 379
Piqray ..... 282
pirfenidone oral capsule ..... 283
pirfenidone oral tablet 267 mg, 801 mg .. 283
Plegridy intramuscular ..... 284
Plegridy subcutaneous pen injector 125 mcg/0.5 mL, 63 mcg/0.5 mL- 94 mcg/0.5 mL ..... 284
Plegridy subcutaneous syringe 125 mcg/0.5 mL, 63 mcg/0.5 mL- 94 mcg/0.5 mL .. 284
Plenamine ..... 450
plerixafor ..... 450
Polivy ..... 285
Pomalyst ..... 286
Portrazza ..... 450
posaconazole oral tablet,delayed release (DR/EC) ..... 287
Poteligeo ..... 288
Prehevbrio (PF) ..... 450
Premasol 10 % ..... 450
Prevymis intravenous ..... 289
Prevymis oral ..... 289
Privigen ..... 171
Procrit ..... 103, 104
Prograf intravenous ..... 450
Prograf oral granules in packet ..... 450
Prolastin-C ..... 17
Prolia ..... 290, 291
Promacta ..... 292, 293
promethazine oral ..... 142
Pulmozyme ..... 450
pyrimethamine ..... 294

**Q**

Qinlock ..... 295

Qulipta ..... 296
**R**
Radicava ORS ..... 297, 298
Radicava ORS Starter Kit Susp ..... 297, 298
Recombivax HB (PF) ..... 450
Remicade ..... 301, 302, 303
Repatha ..... 306, 307
Repatha Pushtronex ..... 306, 307
Repatha SureClick ..... 306, 307
Retacrit ..... 103, 104
Retevmo oral capsule 40 mg, 80 mg 308, 309
Revcovi ..... 310
Rezlidhia ..... 311
Rezurock ..... 312
riluzole ..... 313
Rinvoq oral tablet extended release 24 hr 15 mg, 30 mg, 45 mg ..... 314, 315
roflumilast ..... 316
romidepsin intravenous recon soln ..... 450
Rozlytrek oral capsule 100 mg, 200 mg . 317
Rozlytrek oral pellets in packet ..... 317
Rubraca ..... 318, 319
rufinamide ..... 320
Ruxience ..... 321
Rybelsus ..... 128
Rybrevant ..... 322
Rydapt ..... 323
Rylaze ..... 324
**S**
Sajazir ..... 150, 151
Sandimmune oral solution ..... 450
Sandostatin LAR Depot intramuscular suspension,extended rel recon .... 325, 326
sapropterin ..... 327
Sarclisa ..... 328
Scemblix oral tablet 20 mg, 40 mg ..... 329
Signifor ..... 330
sildenafil (Pulmonary Arterial Hypertension) intravenous solution 10 mg/12.5 mL ..... 281
sildenafil (Pulmonary Arterial Hypertension) oral tablet 20 mg ..... 281
Simulect ..... 450
sirolimus ..... 450
Sirturo ..... 331
Skyrizi intravenous ..... 332, 333
Skyrizi subcutaneous pen injector .. 332, 333
Skyrizi subcutaneous syringe 150 mg/mL ..... 332, 333
Skyrizi subcutaneous wearable injector 180 mg/1.2 mL (150 mg/mL), 360 mg/2.4 mL (150 mg/mL) ..... 332, 333
sodium nitroprusside ..... 450
sodium oxybate ..... 430
sodium phenylbutyrate ..... 279
Somatuline Depot ..... 196, 197
Somavert ..... 335
sorafenib ..... 336, 337
Spravato nasal spray,non-aerosol 56 mg (28 mg x 2), 84 mg (28 mg x 3) ..... 338, 339
Sprycel oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg ..... 340
Stelara intravenous ..... 341, 342
Stelara subcutaneous solution ..... 341, 342
Stelara subcutaneous syringe 45 mg/0.5 mL, 90 mg/mL ..... 341, 342
Stivarga ..... 343, 344
Strensiq ..... 345, 346
streptomycin ..... 19, 20
Sucraid ..... 347, 348
sulfamethoxazole-trimethoprim intravenous ..... 19, 20
sunitinib malate ..... 349, 350
Symdeko ..... 351
SymlinPen 120 ..... 352
SymlinPen 60 ..... 352
Sympazan ..... 65
**T**
Tabrecta ..... 353
tacrolimus oral ..... 450
tacrolimus topical ..... 379
tadalafil (pulm. hypertension) ..... 281
Tafinlar oral capsule ..... 355, 356
Tafinlar oral tablet for suspension .. 355, 356

Tagrisso ..... 357, 358
Taltz Autoinjector ..... 359, 360
Taltz Autoinjector (2 Pack) ..... 359, 360
Taltz Autoinjector (3 Pack) ..... 359, 360
Taltz Syringe ..... 359, 360
Talvey ..... 361
Talzenna ..... 362
Tasigna oral capsule 150 mg, 200 mg, 50 mg ..... 363, 364
tasimelteon ..... 137
tazarotene topical cream ..... 365
tazarotene topical gel ..... 365
Tazicef ..... 19, 20
Tazverik ..... 366
Tecentriq ..... 450
Tecvayli ..... 367
Teflaro ..... 19, 20
Temodar intravenous ..... 450
temsirolimus ..... 450
Tepmetko ..... 368
teriflunomide ..... 27
teriparatide subcutaneous pen injector 20 mcg/dose (620mcg/2.48mL) ..... 369, 370
testosterone cypionate ..... 163, 164
testosterone enanthate ..... 163, 164
testosterone transdermal gel ..... 245, 246
testosterone transdermal gel in metered-dose pump 10 mg/0.5 gram /actuation, 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %) ..... 245, 246
testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram), 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram) ..... 245, 246
testosterone transdermal solution in metered pump w/app ..... 245, 246
tetrabenazine oral tablet 12.5 mg, 25 mg 371
Thalomid oral capsule 100 mg, 150 mg, 200 mg, 50 mg ..... 372, 373
thiotepa ..... 450
Tibsovo ..... 374, 375
Tice BCG ..... 450
tigecycline ..... 19, 20
Tivdak ..... 376
tobramycin in 0.225 % NaCl ..... 377
tobramycin inhalation ..... 377
tobramycin sulfate injection recon soln ... 19, 20
tobramycin sulfate injection solution .. 19, 20
tolvaptan ..... 378
topiramate oral capsule, sprinkle ..... 381
topiramate oral tablet ..... 381
topotecan ..... 450
Travasol 10 % ..... 450
Trazimera ..... 451
Trelstar intramuscular suspension for reconstitution ..... 385
treprostinil sodium ..... 304, 305
tretinoin topical ..... 380
trientine oral capsule 250 mg ..... 386, 387
Trikafta oral granules in packet, sequential ..... 388
Trikafta oral tablets, sequential ..... 388
Trodelvy ..... 389
TrophAmine 10 % ..... 451
Trulicity ..... 128
Truqap ..... 390
Tukysa oral tablet 150 mg, 50 mg ..... 391
Turalio oral capsule 125 mg ..... 392
Tyvaso ..... 451
Tyvaso Institutional Start Kit ..... 451
Tyvaso Refill Kit ..... 451
Tyvaso Starter Kit ..... 451

**U**

Ubrelvy ..... 393
Unituxin ..... 451
Uptravi oral ..... 394

**V**

Valchlor ..... 395
valrubicin ..... 451
Valtoco ..... 396
vancomycin in 0.9 % sodium chl intravenous piggyback 1 gram/200 mL, 500 mg/100 mL, 750 mg/150 mL ... 19, 20

vancomycin injection ..... 19, 20
vancomycin intravenous recon soln 1,000 mg, 10 gram, 5 gram, 500 mg, 750 mg 19, 20
vancomycin oral capsule 125 mg, 250 mg ..... 397
Vanflyta ..... 398
Varubi ..... 451
Vectibix ..... 451
Veletri ..... 451
Venclexta oral tablet 10 mg, 100 mg, 50 mg ..... 399
Venclexta Starting Pack ..... 399
Verzenio ..... 400, 401
Vibativ intravenous recon soln 750 mg ... 19, 20
vigabatrin ..... 402
Vigadrone ..... 402
Vigpoder ..... 402
Vimizim ..... 403
vinblastine ..... 451
vincristine ..... 451
vinorelbine ..... 451
Vistogard ..... 404
Vitrakvi oral capsule 100 mg, 25 mg ..... 405
Vitrakvi oral solution ..... 405
Vizimpro ..... 406
Vonjo ..... 407
voriconazole ..... 21, 408
Vosevi ..... 409
Votrient ..... 410, 411
Vumerity ..... 412
Vyndamax ..... 354
Vyxeos ..... 451
**W**
Welireg ..... 413, 414
**X**
Xalkori oral capsule ..... 415, 416
Xalkori oral pellet 150 mg, 20 mg, 50 mg ..... 415, 416
Xatmep ..... 451
Xdemvy ..... 417
Xeljanz oral solution ..... 418, 419
Xeljanz oral tablet ..... 418, 419
Xeljanz XR ..... 418, 419
Xermelo ..... 420
Xgeva ..... 451
Xiaflex ..... 421, 422
Xolair subcutaneous auto-injector 150 mg/mL, 300 mg/2 mL, 75 mg/0.5 mL 423, 424, 425
Xolair subcutaneous recon soln ..... 423, 424, 425
Xolair subcutaneous syringe 150 mg/mL, 300 mg/2 mL, 75 mg/0.5 mL ..... 423, 424, 425
Xospata ..... 426
Xpovio oral tablet 100 mg/week (50 mg x 2), 40 mg/week (40 mg x 1), 40mg twice week (40 mg x 2), 60 mg/week (60 mg x 1), 60mg twice week (120 mg/week), 80 mg/week (40 mg x 2), 80mg twice week (160 mg/week) ..... 427, 428
Xtandi oral capsule ..... 429
Xtandi oral tablet 40 mg, 80 mg ..... 429
**Y**
Yervoy ..... 451
Yondelis ..... 451
**Z**
Zaltrap ..... 451
Zanosar ..... 451
Zarxio ..... 431, 432
Zejula oral capsule ..... 433
Zejula oral tablet 100 mg, 200 mg, 300 mg ..... 433
Zelboraf ..... 434, 435
Zeposia ..... 436
Zeposia Starter Kit (28-day) ..... 436
Zeposia Starter Pack (7-day) ..... 436
Zepzelca ..... 437
Ziextenzo ..... 438, 439
Zirabev ..... 451
Zoladex ..... 129
zoledronic acid intravenous solution ..... 451

zoledronic acid-mannitol-water intravenous piggyback 4 mg/100 mL ..... 451
zoledronic acid-mannitol-water intravenous piggyback 5 mg/100 mL ..... 299, 300
Zolinza ..... 440
Zonisade ..... 381
zonisamide ..... 381
Ztalmy ..... 441
Zurzuvae ..... 442
Zydelig ..... 443
Zykadia ..... 444
Zynlonta ..... 445
Zynyz ..... 446

Health Insurance Plan of Greater New York (HIP) is an HMO plan with a Medicare contract and a HMO D-SNP plan with a Medicare contract and a contract with the New York State Department of Health. Enrollment in HIP depends on contract renewal. HIP is an EmblemHealth company. EmblemHealth Plan, Inc. is a PPO plan with a Medicare contract. Enrollment in EmblemHealth Plan, Inc. depends on contract renewal.
Note to existing members: This formulary has changed since last year. Please review this document to make sure that it still contains the drugs you take.

Beneficiaries must use network pharmacies to access their premium and/or copayment/coinsurance may change on January 1, 2025. The formulary and pharmacy network may change at any time. You will receive notice when necessary.

This document includes EmblemHealth Medicare HMO/PPO partial formulary as of May 1, 2024. For a complete, updated formulary, please visit our Web site at www.emblemhealth.com/medicare or call the Customer Service number below.

EmblemHealth Medicare HMO: 1-877-344-7364, Monday through Sunday, 8 am to 8 pm.
EmblemHealth Medicare PPO: 1-866-557-7300, Monday through Sunday, 8 am to 8 pm.

TTY users should call 711.

24238v12