

## 2025 Prior Authorization Criteria

Updated 07/01/2025

# 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 end of plan year   |
| Other Criteria               | <p>INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA) [A or B]: A) tried two of the following: Enbrel, preferred adalimumab product, Rinvoq or Xeljanz/XR (Note: trials with the following will also count towards meeting the try two requirement: Cimzia, infliximab, golimumab SC/IV, non-preferred adalimumab product), or B) heart failure or a previously treated lymphoproliferative disorder.</p> <p>POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A or B]: A) tried two of the following: Enbrel, Rinvoq, Xeljanz, preferred adalimumab product. (Note: trials with infliximab or a non-preferred adalimumab product will also count towards meeting the try two requirement), or B) heart failure or a previously treated lymphoproliferative disorder.</p> <p>SYSTEMIC-ONSET JIA (SJIA) [A or B]: A) tried one other systemic agent (e.g., corticosteroid [CS], conventional synthetic DMARD [e.g., MTX, leflunomide, sulfasalazine] or a biologic DMARD [e.g., a TNF inhibitor such as Enbrel, a preferred adalimumab product, or Inflectra] or B) one-month trial of an NSAID.</p> <p>GIANT CELL ARTERITIS: tried one systemic CS.</p> <p>INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) elevated acute phase reactants and B) diagnosis confirmed by high-resolution computed tomography.</p> <p>CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy.</p> |

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

# ACTIMMUNE

## Products Affected

- Actimmune

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

# ADALIMUMAB

## Products Affected

- Cyltezo(CF)
- Cyltezo(CF) Pen
- Cyltezo(CF) Pen Crohn's-UC-HS
- Cyltezo(CF) Pen Psoriasis-UV
- Humira Pen
- Humira Pen Psor-Uveits-Adol HS
- Humira subcutaneous syringe kit 40 mg/0.8 mL
- Humira(CF)
- Humira(CF) Pen
- Humira(CF) Pen Crohns-UC-HS
- Humira(CF) Pen Psor-Uv-Adol HS
- Yuflyma(CF)
- Yuflyma(CF) AI Crohn's-UC-HS
- Yuflyma(CF) Autoinjector

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

| PA Criteria                | Criteria Details   |
|----------------------------|--|
| <b>Other Criteria</b>      | <p>INITIAL THERAPY: CROHN'S DISEASE (CD) [one of A, B, C, or D]: A) tried or currently taking corticosteroid (CS) or CS is contraindicated, B) tried one other conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX], certolizumab, infliximab, ustekinumab, vedolizumab), C) had ileocolonic resection, or D) enterocutaneous (perianal or abdominal) or rectovaginal fistulas. JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA (one of A, B, C, D, or E): A) tried one other systemic therapy (e.g., MTX, sulfasalazine, leflunomide, NSAID), B) tried a biologic (e.g., etanercept, abatacept, infliximab, anakinra, tocilizumab), C) will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide, D) patient has absolute contraindication to MTX, sulfasalazine, or leflunomide, or E) patient has aggressive disease.</p> <p>HIDRADENITIS SUPPURATIVA (HS): tried one other therapy (e.g., intralesional or oral CS, systemic antibiotics, isotretinoin). PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of a biologic will also count) or B) contraindication to MTX. RHEUMATOID ARTHRITIS (RA): tried one conventional synthetic DMARD for at least 3 months (Note: a 3-month trial of a biologic will also count). ULCERATIVE COLITIS (A or B): A) tried a systemic therapy (e.g., 6-MP, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a CS) or B) has pouchitis and tried therapy with an antibiotic, probiotic, CS enema, or mesalamine (Rowasa) enema. BEHCET'S DISEASE (A or B): A) tried one conventional therapy (e.g., systemic CS, azathioprine, MTX, CSA, chlorambucil, cyclophosphamide, interferon alfa), or B) has ophthalmic manifestations. SARCOIDOSIS (A and B): A) tried one CS, and B) tried one immunosuppressant (e.g. MTX, mycophenolate mofetil, chlorambucil, thalidomide, infliximab, chloroquine). SCLERITIS/STERILE CORNEAL ULCERATION: tried one other therapy (e.g. CS, CSA). NON RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation defined as either (A or B): A) C-reactive protein elevated beyond upper limit of normal, or B) sacroiliitis on MRI. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy.</p> |
| <b>Indications</b>         | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>      | Behcet's disease, pyoderma gangrenosum, sarcoidosis, scleritis/sterile corneal ulceration, non-radiographic axial spondyloarthritis.   |
| <b>Part B Prerequisite</b> | 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 |  |
| Age Restrictions             |  |
| 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               |  |
| Part B Prerequisite          | No   |

# AIMOVIG

## Products Affected

- Aimovig Autoinjector

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Combination therapy with another cGRP inhibitor for migraine headache prevention   |
| Required Medical Information | Diagnosis, number of migraine headaches per month  |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| Coverage Duration            | 1 year   |
| Other Criteria               | Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) If pt is currently taking Aimovig, the pt has had significant clinical benefit from the medication. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |
| Part B Prerequisite          | No   |

# AKEEGA

## Products Affected

- Akeega

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



# ALDURAZYME

## Products Affected

- Aldurazyme

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

# ALECENSA

## Products Affected

- Alecensa

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Pediatric diffuse high grade glioma- less than or equal to 21 years old, All others- 18 years and older  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | Non-small cell lung cancer-approve if the patient has both (A and B): A) either (i or ii): i) medication is used as adjuvant treatment following tumor resection (note: for tumors greater than or equal to 4 cm or node positive) or ii) advanced or metastatic disease and B) anaplastic lymphoma kinase (ALK)-positive disease as detected by an approved test. Anaplastic large cell lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease and (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor- pt has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) pt has advanced, recurrent or metastatic disease, or (ii) tumor is inoperable. Large B-Cell Lymphoma- pt has ALK-positive disease AND pt has relapsed or refractory disease. Pediatric diffuse high grade glioma- approve if (A and B): A) ALK-positive disease, and B) either (i or ii): i) medication is used as adjunctive treatment AND tumor is not diffuse midline glioma, H3 K27-altered or pontine location, or ii) medication is used for recurrent or progressive disease. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |

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

# ALOSETRON

## Products Affected

- alosetron

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

# ALPHA 1 PROTEINASE INHIBITORS

## Products Affected

- Prolastin-C intravenous solution

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis  |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| 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               |  |
| Part B Prerequisite          | No   |

# ALUNBRIG

## Products Affected

- Alunbrig

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

## ANTIFUNGALS (IV)

### Products Affected

- voriconazole

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

# ANTI-OBESITY AGENTS

## Products Affected

- ADIPEX-P 37.5 MG TABLET
- BENZPHETAMINE HCL 50 MG TABLET (Rx)
- DIETHYLPROPION 25 MG TABLET
- DIETHYLPROPION ER 75 MG TABLET
- IMCIVREE 10 MG/ML VIAL
- LOMAIRA 8 MG TABLET
- ORLISTAT 120 MG CAPSULE
- PHENDIMETRAZINE 35 MG TABLET
- PHENDIMETRAZINE ER 105 MG CAP
- PHENTERMINE 15 MG CAPSULE
- PHENTERMINE 30 MG CAPSULE
- PHENTERMINE 37.5 MG CAPSULE
- PHENTERMINE 37.5 MG TABLET
- SAXENDA 18 MG/3 ML PEN
- WEGOVY 0.25 MG/0.5 ML PEN OUTER,SUV
- WEGOVY 0.5 MG/0.5 ML PEN OUTER,SUV
- WEGOVY 1 MG/0.5 ML PEN OUTER,SUV
- WEGOVY 1.7 MG/0.75 ML PEN OUTER,SUV
- WEGOVY 2.4 MG/0.75 ML PEN OUTER,SUV
- XENICAL 120 MG CAPSULE

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent use of Wegovy and Saxenda with other GLP-1 receptor agonists.  |
| <b>Required Medical Information</b> | Initial: For agents other than Imcivree, patient must have a body mass index [BMI] greater than or equal to 30 kg/m2, OR Patient must have a body mass index [BMI] greater than or equal to 27 kg/m2 but less than 30 kg/m2 and at least one of the following risk factors: hypertension, cardiovascular disease (CVD, including coronary artery disease), diabetes, dyslipidemia, or sleep apnea, OR For Imcivree, pediatric patients must have an initial BMI greater than the 95th percentile for age and sex for obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency and greater than the 97th percentile for age and sex for obesity due to Bardet-Biedl syndrome (BBS), OR For Wegovy or Xenical, pediatric patients must have an initial BMI at the 95th percentile or greater for age and sex (obesity),<br>Renewal: Prescriber attests that patient has maintained a loss of greater than or equal to 5% from baseline weight (adults) or baseline BMI (pediatrics) at initiation of therapy. |
| <b>Age Restrictions</b>             | Patient age greater than or equal to 12 years (Wegovy, Xenical, Saxenda), OR Patient age greater than or equal to 18 years (Contrave, benzphetamine, diethylpropion, phentermine, phendimetrazine), OR Patient age greater than or equal to 6 years (Imcivree).   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 6 months  |



| <b>PA Criteria</b>         | <b>Criteria Details</b>  |
|----------------------------|--|
| <b>Other Criteria</b>      | Prescriber attests to patients absence of any contraindications to use of the requested product, AND Prescriber attests that the patient is not pregnant or lactating, AND Prescriber attests that at least one previously documented weight reduction attempt in the past year, AND Prescriber attests medication therapy is part of a total treatment plan including a calorie and fat restricted diet and exercise regimen. |
| <b>Indications</b>         | Some FDA-approved Indications Only.  |
| <b>Off Label Uses</b>      |  |
| <b>Part B Prerequisite</b> | No   |

# ARCALYST

## Products Affected

- Arcalyst

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | Concurrent biologic therapy   |
| Required Medical Information |   |
| Age Restrictions             | Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age.  |
| Prescriber Restrictions      | Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA initial-rheum, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum             |
| Coverage Duration            | CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont   |
| Other Criteria               | INITIAL THERAPY: DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) [all of A and B]: A) weighs at least 10 kg and B) genetic test confirms a mutation in the IL1RN gene. PERICARDITIS: pericarditis is recurrent. CONTINUATION THERAPY: ALL INDICATIONS: patient had a positive response to therapy. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |
| Part B Prerequisite          | No  |

# ARIKAYCE

## Products Affected

- Arikayce

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis, previous medication history (as described in Other Criteria field)   |
| <b>Age Restrictions</b>             | MAC-18 years and older (initial therapy)  |
| <b>Prescriber Restrictions</b>      | MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections.   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | INITIAL THERAPY: MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE (all of A, B, and C): A) positive sputum culture for MAC [Note: any positive sputum culture taken after completion of a background multidrug regimen (throughout, see Example 1 below) fulfills this criterion], B) MAC isolate is susceptible to amikacin, and C) Arikayce will be used in combination with a background multidrug regimen. CONTINUATION THERAPY: MAC LUNG DISEASE (A and B): A) Arikayce prescribed in combination with a background multidrug regimen and B) patient meets one of the following (a or b): a) patient has not achieved negative sputum cultures for MAC or b) patient has achieved negative sputum cultures for MAC for less than 12 months. Example 1: background multidrug regimen example - a macrolide (azithromycin or clarithromycin), ethambutol, and a rifamycin (rifampin or rifabutin). |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | 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             |  |
| Prescriber Restrictions      | Prescribed by or in consultation with a neurologist or MS specialist.  |
| Coverage Duration            | Authorization will be for 1 year.  |
| Other Criteria               |  |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |
| Part B Prerequisite          | No   |

# AUGTYRO

## Products Affected

- Augtyro

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis  |
| Age Restrictions             | NSCLC - 18 years and older, Solid tumors - 12 years and older  |
| Prescriber Restrictions      |  |
| 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. Solid tumors - approve if tumor is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND tumor is locally advanced or metastatic or surgical resection will likely result in severe morbidity AND disease has progressed following treatment or there are no satisfactory alternative therapies. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |
| Part B Prerequisite          | No   |

# AUSTEDO

## Products Affected

- Austedo
- Austedo XR
- Austedo XR Titration Kt(Wk1-4) oral tablet, Ext  
Rel 24hr dose pack 12-18-24-30 mg

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

# AYVAKIT

## Products Affected

- Ayvakit

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

# BALVERSA

## Products Affected

- Balversa

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



# BENLYSTA

## Products Affected

- Benlysta

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent Use with Other Biologics or Lupkynis   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | Lupus Nephritis: 18 years and older (initial). SLE: 5 years and older (initial).  |
| <b>Prescriber Restrictions</b>      | SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)   |
| <b>Coverage Duration</b>            | SLE-Initial-4 months, cont-1 year. Lupus Nephritis-6 mo initial, 1 year cont  |
| <b>Other Criteria</b>               | Lupus Nephritis Initial-approve if the patient has a diagnosis of lupus nephritis confirmed on biopsy (For example, World Health Organization class III, IV, or V lupus nephritis), AND the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid). Cont-approve if the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid) AND the patient has responded to Benlysta subcutaneous or intravenous. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA [anti-dsDNA] antibody AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity,. Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity AND The patient has responded to Benlysta subcutaneous or intravenous. |

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

# BETASERON/EXTAVIA

## Products Affected

- Betaseron subcutaneous kit

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

## BEXAROTENE (ORAL)

### Products Affected

- bexarotene

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

## BEXAROTENE (TOPICAL)

### Products Affected

- bexarotene

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | Adult T-Cell Leukemia/Lymphoma- approve if the patient has chronic/smoldering subtype and this medication is used as first-line therapy. Primary cutaneous B-Cell lymphoma-approve if used as skin-directed therapy for either (a or b): a) primary cutaneous marginal zone lymphoma or b) follicle center lymphoma. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Adult T-Cell Leukemia/Lymphoma, Primary Cutaneous B-Cell Lymphoma  |
| <b>Part B Prerequisite</b>          | No   |

# BOSENTAN/AMBRISENTAN

## Products Affected

- ambrisentan
- bosentan

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

# BOSULIF

## Products Affected

- Bosulif

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



# BRAFTOVI

## Products Affected

- Braftovi

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis, BRAF V600 status  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | <p>Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. Colon or Rectal cancer-approve if the patient meets the following (A and B): A) The patient has BRAF V600E mutation-positive disease AND B) meets (i or ii): i) will be used as first-line systemic therapy for metastatic disease in combination with an anti-EGFR therapy and mFOLFOX6 (5-FU, leucovorin, and oxaliplatin) or ii) patient has previously received a chemotherapy regimen for colon or rectal cancer and this is prescribed as part of a combination regimen for colon or rectal cancer.</p> <p>NSCLC- approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets).</p> <p>Appendiceal adenocarcinoma-approve if (A, B and C): A) BRAF V600E mutation-positive, and B) used as subsequent therapy for advanced or metastatic disease, and C) used in combination with an anti-EGFR therapy. Note: Examples of anti-EGFR therapy includes Erbitux (cetuximab intravenous infusion) and Vectibix (panitumumab intravenous infusion).</p> |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Appendiceal adenocarcinoma   |
| <b>Part B Prerequisite</b>          | No   |

# BRUKINSA

## Products Affected

- Brukinsa

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis, prior therapies  |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Follicular Lymphoma - approve if pt tried at least two other systemic regimens and will use this in combination with Gazyva (obinutuzumab intravenous infusion). Mantle Cell Lymphoma/CLL/SLL - approve. Marginal zone lymphoma-approve if the patient has tried at least one systemic regimen. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma-approve. Hairy Cell Leukemia - approve if pt has received therapy for relapsed or refractory disease AND pt has progressive disease. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Hairy Cell Leukemia   |
| <b>Part B Prerequisite</b>          | No  |

# BUPRENORPHINE

## Products Affected

- buprenorphine HCl sublingual

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | The requested drug is being prescribed for the treatment of opioid use disorder AND patient meets one of the following: 1) The patient is pregnant or breastfeeding, and the requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for treatment of opioid use disorder OR 2) The requested drug is being prescribed for induction therapy for transition from opioid use to treatment of opioid use disorder OR 3) The requested drug is being prescribed for maintenance therapy for treatment of opioid use disorder in in a patient who is intolerant to buprenorphine/naloxone. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# C1 ESTERASE INHIBITORS

## Products Affected

- Haegarda

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders  |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | 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 Haegarda for prophylaxis - approve if the patient meets the following criteria (i and ii): i) patient has a diagnosis of HAE type I or II, and ii) according to the prescriber, the patient has had a favorable clinical response since initiating Haegarda as prophylactic therapy compared with baseline. For patients with HAE with normal C1 inhibitor, EITHER 1) Patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# CABOMETYX

## Products Affected

- Cabometyx

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis, histology, RET gene rearrangement status for NSCLC  |
| <b>Age Restrictions</b>             | Neuroendocrine tumor/Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | <p>Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried Lenvima or sorafenib. Endometrial carcinoma-approve if the patient has tried one systemic regimen. GIST-approve if the patient has tried two of the following-imatinib, Ayvakit, sunitinib, dasatinib, Stivarga or Qinlock. NSCLC-approve if the patient has RET rearrangement positive tumor. Neuroendocrine tumors- approve if (A and B): A) pt has locally advanced, unresectable, or metastatic disease, and B) meets (i or ii): i) patient has well-differentiated neuroendocrine tumors, or ii) patient has pancreatic or extra-pancreatic neuroendocrine tumors and the medication will be used as subsequent therapy. Adrenal gland tumor- approve if pt has locoregional unresectable or metastatic adrenocortical carcinoma. Pheochromocytoma/paraganglioma- approve if pt has locally unresectable disease.</p> |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |

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

# CALQUENCE

## Products Affected

- Calquence
- Calquence (acalabrutinib mal)

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | 1 year   |
| Other Criteria               | CLL and SLL-approve. Mantle Cell Lymphoma- approve if the patient meets (A or B): A) has tried at least one systemic regimen or is not a candidate for a systemic regimen (e.g., rituximab, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, bortezomib, or lenalidomide) or B) this medication is used in combination with rituximab. Marginal Zone Lymphoma-approve if patient has tried at least one systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, lenalidomide, or chlorambucil). Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen (e.g., Brukinsa [zanubrutinib capsules], Imbruvica [ibrutinib tablets and capsules], rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, fludarabine, or cladribine) |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| Off Label Uses               | Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma.  |
| Part B Prerequisite          | No   |

# CAPRELSA

## Products Affected

- Caprelsa

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



# CARGLUMIC ACID

## Products Affected

- carglumic acid

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

# CAYSTON

## Products Affected

- Cayston

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

# CLOBAZAM

## Products Affected

- clobazam oral suspension
- clobazam oral tablet
- Sympazan

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

# CLOMIPRAMINE

## Products Affected

- clomipramine

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | 1) The requested drug is being prescribed for one of the following: a) Obsessive-Compulsive Disorder (OCD), b) Panic Disorder AND 2) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to any of the following: a) a serotonin and norepinephrine reuptake inhibitor (SNRI), b) a selective serotonin reuptake inhibitor (SSRI) OR 3) The requested drug is being prescribed for Depression AND 4) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: a) serotonin and norepinephrine reuptake inhibitors (SNRIs), b) selective serotonin reuptake inhibitors (SSRIs), c) mirtazapine, d) bupropion |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Depression, Panic Disorder  |
| <b>Part B Prerequisite</b>          | No  |

# COMETRIQ

## Products Affected

- Cometriq

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis.   |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy and patient has tried a Vascular Endothelial Growth Factor Receptor (VEGFR)-targeted therapy. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma   |
| <b>Part B Prerequisite</b>          | No   |

# COPIKTRA

## Products Affected

- Copiktra

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

# COSENTYX

## Products Affected

- Cosentyx (2 Syringes)
- Cosentyx Pen
- Cosentyx Pen (2 Pens)
- Cosentyx subcutaneous
- Cosentyx UnoReady Pen

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)  |
| <b>Required Medical Information</b> | Diagnosis and previous medications use  |
| <b>Age Restrictions</b>             | PP-6 yr and older. AS/Spondy/HS initial - 18 years of age and older. PsA-2 years and older. Enthesitis-4 years and older  |
| <b>Prescriber Restrictions</b>      | PP initial-presc/consult dermat. PsA initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS/spondylo/enthesitis initial- by or in consultation with rheumatologist. HS initial - by or in consult w/ dermatologist   |
| <b>Coverage Duration</b>            | Approve through end of plan year  |
| <b>Other Criteria</b>               | INITIAL THERAPY: HIDRADENITIS SUPPURATIVA (HS): tried at least one other therapy (e.g. systemic antibiotics, isotretinoin). NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation and meets a or b: a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI. PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of at least one biologic that is not Cosentyx or a Cosentyx biosimilar also counts) or B) contraindication to MTX. CONTINUATION THERAPY: ALL INDICATIONS: patient has experienced benefit from the medication. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# COTELLIC

## Products Affected

- Cotellic

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | <p>Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf AND patient has BRAF V600 mutation positive disease. CNS Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma/neuroglioma/glioneuronal tumor OR ii. Recurrent or progressive disease for one of the following conditions (a or b): a) glioma/circumscribed glioma OR b) Glioblastoma, OR iii. Melanoma with brain metastases AND medication with be taken in combination with Zelboraf (vemurafenib tablets). Histiocytic Neoplasm-approve if the patient meets one of the following (i, ii, or iii): i. Patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease.</p> |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Central Nervous System Cancer   |
| <b>Part B Prerequisite</b>          | No  |



## CRESEMBA (ORAL)

### Products Affected

- Cresemba oral

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

# CYSTEAMINE (OPHTHALMIC)

## Products Affected

- Cystaran

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

# CYSTEAMINE (ORAL)

## Products Affected

- Cystagon

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

# DALFAMPRIDINE

## Products Affected

- dalfampridine

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

# DANZITEN

## Products Affected

- Danziten

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

# DAURISMO

## Products Affected

- Daurismo

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis, medications that will be used in combination, comorbidities |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| 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               |  |
| Part B Prerequisite          | No   |

# DEFERASIROX

## Products Affected

- deferasirox

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

# DHE NASAL

## Products Affected

- dihydroergotamine nasal

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin). |
| Required Medical Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one triptan 5-HT1 receptor agonist.   |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Plan Year  |
| Other Criteria               |  |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |
| Part B Prerequisite          | No   |



# DIACOMIT

## Products Affected

- Diacomit

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

# DIMETHYL FUMARATE

## Products Affected

- dimethyl fumarate

| 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             |   |
| Prescriber Restrictions      | Prescribed by or in consultation with a neurologist or MS specialist.   |
| Coverage Duration            | Authorization will be for 1 year.   |
| Other Criteria               |   |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |
| Part B Prerequisite          | No  |

# DOPTELET

## Products Affected

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

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 years and older (for chronic ITP-initial therapy only)   |
| <b>Prescriber Restrictions</b>      | Chronic ITP-prescribed by or after consultation with a hematologist (initial therapy)   |
| <b>Coverage Duration</b>            | Thrombo w/chronic liver disease-5 days, chronic ITP initial-3 months, cont-1 year   |
| <b>Other Criteria</b>               | THROMBOCYTOPENIA WITH CHRONIC LIVER DISEASE (A and B): A) current platelet count less than 50 x 10 <sup>9</sup> /L and B) scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. CHRONIC ITP, INITIAL THERAPY (A and B): A): (i or ii): i) platelet count less than 30,000 microliters or ii) platelet count less than 50,000 microliters and patient is at an increased risk of bleeding, and B) tried one other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, eltrombopag tablets and oral suspension, romiplostim subcutaneous injection, fostamatinib tablets, rituximab) or had a splenectomy. CHRONIC ITP, CONTINUATION THERAPY: patient had beneficial clinical response and remains at risk for bleeding complications. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# DROXIDOPA

## Products Affected

- droxidopa

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

# DUPIXENT

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## Products Affected

- Dupixent Pen
- Dupixent Syringe

| PA Criteria                  | Criteria Details |
|------------------------------|------------------|
| Exclusion Criteria           | UNDER CMS REVIEW |
| Required Medical Information | UNDER CMS REVIEW |
| Age Restrictions             | UNDER CMS REVIEW |
| Prescriber Restrictions      | UNDER CMS REVIEW |
| Coverage Duration            | UNDER CMS REVIEW |
| Other Criteria               | UNDER CMS REVIEW |
| Indications                  | UNDER CMS REVIEW |
| Off Label Uses               | UNDER CMS REVIEW |
| Part B Prerequisite          | No               |

# ELREXFIO

## Products Affected

- Elrexfio

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

# EMGALITY

## Products Affected

- Emgality Pen
- Emgality Syringe subcutaneous syringe 120 mg/mL

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Combination therapy with another cGRP inhibitor for migraine headache prevention  |
| <b>Required Medical Information</b> | Diagnosis, number of migraine or cluster headaches per month  |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Cluster headache tx-6 months, migraine prevention-1 year  |
| <b>Other Criteria</b>               | Migraine headache prevention-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) If pt is currently taking Emgality, pt has had significant clinical benefit from the medication. Note: Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Emgality was initiated. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# ENBREL

## Products Affected

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

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Concurrent use with biologic therapy or targeted synthetic DMARD   |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous therapies tried.   |
| <b>Age Restrictions</b>             | PP-4 years and older (initial therapy)   |
| <b>Prescriber Restrictions</b>      | Initial 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.  |
| <b>Coverage Duration</b>            | Approve through end of plan year   |
| <b>Other Criteria</b>               | INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA): tried one conventional synthetic DMARD for at least 3 months (see Note 1). JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA (one of A, B, C, or D): A) patient has aggressive disease, B) tried one other systemic therapy (e.g., methotrexate [MTX], sulfasalazine, leflunomide, NSAID, or a biologic that is not a biosimilar of the requested product), C) patient will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide, or D) patient has an absolute contraindication to MTX, sulfasalazine, or leflunomide. PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent for at least 3 months, unless intolerant (e.g., MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA) [see Note 1] or B) patient has a contraindication to one oral agent for psoriasis such as MTX. GRAFT VERSUS HOST DISEASE (GVHD): approve. BEHCET'S: tried at least one conventional therapy (e.g., systemic corticosteroid, immunosuppressant, interferon alfa, mycophenolate), adalimumab, or infliximab. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Note 1: a biologic that is not a biosimilar of the requested product will also count. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |



|                                |  |
|--------------------------------|--|
| <b>PA Criteria</b>             | <b>Criteria Details</b>                            |
| <b>Off Label Uses</b>          | Graft versus host disease (GVHD), Behcet's disease |
| <b>Part B<br/>Prerequisite</b> | No   |

# ENDARI

## Products Affected

- glutamine (sickle cell)

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| 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               |   |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |
| Part B Prerequisite          | No  |

# EPIDIOLEX

## Products Affected

- Epidiolex

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

# EPOETIN ALFA

## Products Affected

- Retacrit

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | MDS anemia = 18 years of age and older   |
| <b>Prescriber Restrictions</b>      | MDS anemia, myelofibrosis- prescribed by or in consultation with, a hematologist or oncologist.  |
| <b>Coverage Duration</b>            | Chemo-6m,Transfus-1m, CKD-1yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr   |
| <b>Other Criteria</b>               | Anemia in a pt with Chronic Kidney Disease (CKD) not on dialysis- for initial therapy, approve if hemoglobin (Hb) is less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children, or for continuation of therapy in a pt currently on an erythropoiesis-stimulating agent (ESA) approve if Hb is less than or equal to 12 g/dL. Anemia in a pt with cancer due to chemotherapy- approve if pt is currently receiving myelosuppressive chemo as a non-curative treatment and (for initial therapy) Hb is less than 10.0 g/dL or (if currently on ESA) Hb is less than or equal to 12.0 g/dL. Anemia in HIV with zidovudine- for initial therapy, approve if Hb is less than 10.0 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA, approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Approve if Hb is less than or equal to 13, AND surgery is elective, nonvascular and non-cardiac AND pt is unwilling or unable to donate autologous blood prior to surgery. MDS- for initial therapy, approve if Hb is less than 10 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA approve if Hb is 12.0 g/dL or less. Myelofibrosis- for Initial therapy approve if patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 mU/mL, or for continuation of therapy in pt currently on ESA hemoglobin is less than or equal to 12g/dL. Anemia in patients with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit). |

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

# ERIVEDGE

## Products Affected

- Erivedge

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

# ERLEADA

## Products Affected

- Erleada

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# ERLOTINIB

## Products Affected

- erlotinib

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Authorization will be for 1 year   |
| <b>Other Criteria</b>               | Advanced or Metastatic NSCLC, approve if the patient has EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note- Examples of EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. RCC, approve if the patient has recurrent or advanced non-clear cell histology RCC or if the patient had hereditary leiomyomatosis and renal cell carcinoma and erlotinib will be used in combination with bevacizumab. Bone cancer-approve if the patient has chordoma and has tried at least one previous therapy. Pancreatic cancer-approve if the medication is used in combination with gemcitabine and if the patient has locally advanced, metastatic or recurrent disease. Vulvar cancer-approve if the patient has advanced, recurrent or metastatic disease. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma.  |
| <b>Part B Prerequisite</b>          | No   |



# EVEROLIMUS

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## Products Affected

- everolimus (antineoplastic)

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| 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      |   |
| Coverage Duration            | Authorization will be for 1 year  |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>Breast Cancer-approve if pt meets ALL the following (A, B, C, D, E, and F):A)pt has recurrent or metastatic,HR+ disease AND B)pt has HER2-negative breast cancer AND C)pt has tried at least 1 prior endocrine therapy AND D)pt meets 1 of the following conditions (i or ii):i.pt is a postmenopausal woman or man OR ii.pt is pre/perimenopausal woman AND is receiving ovarian suppression/ablation with a GnRH agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND E)pt meets 1 of the following conditions (i or ii): i.Everolimus will be used in combo with exemestane and pt meets 1 of the following:pt is male and is receiving a GnRH analog or pt is a woman or ii. Everolimus will be used in combo with fulvestrant or tamoxifen AND F)pt has not had disease progression while on Everolimus. RCC, relapsed or Stage IV disease-approve if using for non-clear cell disease or if using for clear cell disease, pt has tried 1 prior systemic therapy (e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).TSC Associated SEGA-approve if pt requires therapeutic intervention but cannot be curatively resected. Thymomas and Thymic Carcinomas-approve if pt has tried chemotherapy or cannot tolerate chemotherapy.TSC associated renal angiomyolipoma -approve. WM/LPL - approve if pt has progressive or relapsed disease or if pt has not responded to primary therapy. Thyroid Carcinoma, differentiated-approve if pt is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if everolimus will be used in combo with letrozole. GIST-approve if pt has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock or imatinib AND there is confirmation that everolimus will be used in combo with 1 of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. TSC-associated partial-onset seizures-approve. NET tumors of the pancreas, GI Tract, Lung and Thymus (carcinoid tumors)-approve. Soft tissue sarcoma-approve if pt has perivascular epithelioid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangiomyomatosis. Classic hodgkin lymphoma-approve if pt has relapsed or refractory disease AND has tried at least three prior lines of chemotherapy. Histiocytic neoplasm-approve if pt has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis. Patient must also have PIK3CA mutation. Meningioma- approve if pt has recurrent or progressive disease AND pt has surgically inaccessible disease and radiation therapy is not possible AND medication will be used in combination with a somatostatin analogue. Uterine Sarcoma-approve if the</p> |
|                       | <p>patient has advanced, recurrent, metastatic, or inoperable disease, AND has a perivascular epithelioid cell tumor (PEComa), AND has tried at least one systemic regimen. Note: Examples of systemic regimen include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine.</p>  |
| <b>Indications</b>    | All FDA-approved Indications, Some Medically-accepted Indications.  |

| PA Criteria                | Criteria Details   |
|----------------------------|--|
| <b>Off Label Uses</b>      | neuroendocrine tumors of the thymus (Carcinoid tumors). Soft tissue sarcoma, classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST), men with breast cancer, Pre-peri-menopausal women with breast cancer, Histiocytic Neoplasm, uterine sarcoma, meningioma |
| <b>Part B Prerequisite</b> | No   |

# EXKIVITY

## Products Affected

- Exkivity

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Non-Small Cell Lung Cancer (NSCLC)-approve if the patient meets (A, B and C):<br>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. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# FABRAZYME

## Products Affected

- Fabrazyme

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

# FASENRA

## Products Affected

- Fasenra
- Fasenra Pen

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

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

# FINGOLIMOD

## Products Affected

- fingolimod

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



# FINTEPLA

## Products Affected

- Fintepla

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

# FIRMAGON

## Products Affected

- Firmagon kit w diluent syringe

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis  |
| Age Restrictions             |  |
| 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               |  |
| Part B Prerequisite          | No   |

# FLUCYTOSINE

## Products Affected

- flucytosine

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

# FOTIVDA

## Products Affected

- Fotivda

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

# FRUZAQLA

## Products Affected

- Fruzaqla

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 years of age and older   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Colon cancer, rectal cancer, or appendiceal cancer-Approve if the patient meets the following (A and B): A) Patient has advanced or metastatic disease, AND B) Patient has previously been treated with the following (i, ii, and iii): i. Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine. AND ii. An anti-vascular endothelial growth factor (VEGF) agent, Note: Examples of anti-VEGF agents include bevacizumab. AND iii. If the tumor is RAS wild-type (KRAS wild-type and NRAS wild-type) [that is, the tumor or metastases are KRAS and NRAS mutation negative], the patient meets ONE of the following (a or b): a) According to the prescriber, anti-epidermal growth factor receptor (EGFR) therapy is NOT medically appropriate, OR b) The patient has received an anti-EGFR therapy. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Appendiceal cancer  |
| <b>Part B Prerequisite</b>          | No  |

# GATTEX

## Products Affected

- Gattex 30-Vial
- Gattex One-Vial

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | 1 year and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a gastroenterologist (initial and continuation)  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | 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.<br>Continuation-approve if the patient has experienced improvement. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# GAVRETO

## Products Affected

- Gavreto

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

# GEFITINIB

## Products Affected

- gefitinib

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | 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. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | NSCLC with EGFR L861Q, G719X, or S768I mutations.  |
| <b>Part B Prerequisite</b>          | No   |



# GILOTRIF

## Products Affected

- Gilotrif

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | For NSCLC - EGFR exon deletions or mutations, or if NSCLC is squamous cell type  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Authorization will be for 1 year   |
| <b>Other Criteria</b>               | NSCLC EGFR pos - For the treatment of advanced or metastatic non small cell lung cancer (NSCLC)-approve if the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: examples of sensitizing EGFR mutation-positive NSCLC include the following mutations : exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. NSCLC metastatic squamous cell must have disease progression after treatment with platinum based chemotherapy. Head and neck cancer-approve if the patient has non-nasopharyngeal head and neck cancer and the patient has disease progression on or after platinum based chemotherapy. (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan) |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Head and neck cancer   |
| <b>Part B Prerequisite</b>          | Yes  |

# GLATIRAMER

## Products Affected

- glatiramer
- Glatopa

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

# GLUCAGON-LIKE PEPTIDE-1 AGONISTS

## Products Affected

- Bydureon BCise
- Mounjaro
- Ozempic
- Rybelsus
- Trulicity

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

# GOMEKLI

## Products Affected

- Gomekli

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

# GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

## Products Affected

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

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

# GRALISE

## Products Affected

- gabapentin oral tablet extended release 24 hr

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

# GROWTH HORMONE

## Products Affected

- Omnitrope

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Pediatric patients with closed epiphyses   |
| Required Medical Information | Pediatric growth hormone deficiency (GHD): Patient (pt) is a neonate or was diagnosed with GHD as a neonate OR meets any of the following: 1) younger than 2.5 years old (yo) with pre-treatment (pre-tx) height (ht) more than 2 standard deviations (SD) below mean and slow growth velocity OR 2) 2.5 yo or older AND one of the following: a) pre-tx 1-year ht velocity more than 2 SD below mean OR b) pre-tx ht more than 2 SD below mean and 1-year ht velocity more than 1 SD below mean, AND patient meets any of the following: 1) failed 2 pre-tx growth hormone (GH) stimulation tests (peak below 10 ng/mL), OR 2) pituitary/central nervous system (CNS) disorder (e.g., genetic defects, acquired structural abnormalities, congenital structural abnormalities) and pre-tx insulin-like growth factor-1 (IGF-1) more than 2 SD below mean. Turner syndrome: 1) Confirmed by karyotyping AND 2) pre-tx ht is less than the 5th percentile for age. Small for gestational age (SGA): 1) Birth weight (wt) less than 2500g at gestational age (GA) greater than 37 weeks, OR birth wt or length below 3rd percentile for GA or at least 2 SD below mean for GA, AND 2) did not manifest catch-up growth by age 2. |
| Age Restrictions             | SGA: 2 years of age or older   |
| Prescriber Restrictions      | Prescribed by or in consultation with an endocrinologist, pediatric endocrinologist, nephrologist, infectious disease specialist, gastroenterologist/nutritional support specialist, or geneticist.  |
| Coverage Duration            | Plan Year  |

| PA Criteria                | Criteria Details  |
|----------------------------|---|
| <b>Other Criteria</b>      | <p>Adult GHD: Pt meets any of the following: 1) failed 2 pre-tx GH stimulation tests, OR 2) pre-tx IGF-1 more than 2 SD below mean AND failed 1 pre-tx GH stimulation test. (Note: Stimulation tests include: a) insulin tolerance test [ITT] [peak GH less than or equal to 5 ng/ml], or b) Macrilen-stimulation test [peak GH level less than 2.8ng/ml], or c) glucagon-stimulation test [GST] [peak GH level less than or equal to 3 ng/ml] for pt with a body mass index [BMI] 25-30 kg/m<sup>2</sup> and high pretest probability of GHD [e.g., acquired structural abnormalities] or BMI less than 25 kg/m<sup>2</sup>, or d) GST [peak GH level less than or equal to 1 ng/ml] in pt with BMI 25-30 kg/m<sup>2</sup> and low pretest probability of GHD or BMI greater than 30 kg/m<sup>2</sup>), OR 3) organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with 3 or more pituitary hormone deficiencies AND pre-tx IGF-1 more than 2 SD below mean, OR 4) genetic or structural hypothalamic-pituitary defects, OR 5) childhood-onset GHD with congenital (genetic or structural) abnormality of the hypothalamus/pituitary/CNS. Renewal for pediatric GHD, TS, SGA, and adult GHD: Patient is experiencing improvement.</p> |
| <b>Indications</b>         | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>      |   |
| <b>Part B Prerequisite</b> | No  |



# HRM-ANTIPARKINSON

## Products Affected

- benztropine oral
- trihexyphenidyl oral tablet

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. EPS (extrapyramidal symptoms): The patient has tried and experienced an inadequate treatment response, intolerance, or has a contraindication to the non-HRM alternative drug amantadine. Parkinson's: The patient has tried and experienced an inadequate treatment response or intolerance to two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | This Prior Authorization only applies to patients 65 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# HRM-BENZODIAZEPINES

## Products Affected

- clorazepate dipotassium
- Diazepam Intensol
- diazepam oral

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs). |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Short-term relief anx-1 mo, skeletal muscle spasm-3 mo, Anx Disorders-4 mo, Other Diagnoses-PlanYR  |
| <b>Other Criteria</b>               | This Prior Authorization only applies to patients 65 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# HRM-CYCLOBENZAPRINE

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## Products Affected

- cyclobenzaprine oral tablet 10 mg, 5 mg

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | 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.   |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |
| Part B Prerequisite          | No   |

# HRM-CYPROHEPTADINE

## Products Affected

- cyproheptadine oral tablet

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: The patient has tried and experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | This Prior Authorization only applies to patients 65 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)  |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Pruritus, spasticity due to spinal cord injury  |
| <b>Part B Prerequisite</b>          | No  |

# HRM-FIRST GENERATION ANTIHISTAMINES

## Products Affected

- hydroxyzine HCl oral tablet
- hydroxyzine pamoate oral capsule 25 mg, 50 mg
- promethazine oral

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

# HRM-PHENOBARBITAL

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## Products Affected

- phenobarbital

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Coverage is not provided for use in sedation/insomnia.   |
| Required Medical Information |  |
| Age Restrictions             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| Prescriber Restrictions      |  |
| 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               |  |
| Part B Prerequisite          | No   |

# HRM-SCOPOLAMINE

## Products Affected

- scopolamine base

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| Off Label Uses               | Excessive salivation   |
| Part B Prerequisite          | No   |

# HRM-TEMAZEPAM

## Products Affected

- temazepam oral capsule 15 mg, 30 mg, 7.5 mg

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | For short-term treatment of insomnia: The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for the patient.   |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |
| Part B Prerequisite          | No   |



# IBRANCE

## Products Affected

- Ibrance

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Breast cancer - approve recurrent or metastatic, hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, or letrozole 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND meets one of the following conditions: Ibrance will be used in combination with anastrozole, exemestane, or letrozole or Ibrance will be used in combination with fulvestrant 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Ibrance with be used in combination with anastrozole, exemestane or letrozole or Ibrance will be used in combination with fulvestrant 4. Pt is postmenopausal and Ibrance will be used in combination with fulvestrant. Liposarcoma-approve if the patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS). |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Liposarcoma   |
| <b>Part B Prerequisite</b>          | No  |

# ICATIBANT

## Products Affected

- icatibant
- Sajazir

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders   |
| <b>Coverage Duration</b>            | Authorization will be for 1 year.  |
| <b>Other Criteria</b>               | Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant - the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# ICLUSIG

## Products Affected

- Iclusig

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status  |
| <b>Age Restrictions</b>             | All indications except ALL - 18 years and older   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Authorization will be for 1 year  |
| <b>Other Criteria</b>               | Acute lymphoblastic leukemia, Philadelphia chromosome positive or ABL-class translocation-approve. Chronic myeloid leukemia-approve. GIST - approve if the patient tried all of the following therapies first to align with NCCN recommendations which include: Imatinib or Ayvakit (avapritinib tablets), AND Sunitinib or Sprycel (dasatinib tablets), AND Stivarga (regorafenib tablets), AND Qinlock (ripretinib tablets). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has ABL1 rearrangement or FGFR1 rearrangement. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia  |
| <b>Part B Prerequisite</b>          | No  |

# IDHIFA

## Products Affected

- Idhifa

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | IDH2-mutation status  |
| Age Restrictions             | 18 years and older  |
| Prescriber Restrictions      |   |
| 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               |   |
| Part B Prerequisite          | No  |

# IMATINIB

## Products Affected

- imatinib
- Imkeldi

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.  |
| <b>Age Restrictions</b>             | ASM, DFSP, HES, MDS/MPD/Myeloid/Lymphoid Neoplasms/Kaposi Sarcoma/Cutaneous Melanoma-18 years and older   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | For ALL-approve for Ph-positive or ABL-class translocation ALL. CML-approve for Ph-positive or BCR::ABL1-mutation positive CML. Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or Romvimza or according to the prescriber, the patient cannot take Turalio or Romvimza. Myelodysplastic/myeloproliferative disease-approve if the condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.Graft versus host disease, chronic-approve if the patient has tried at least one conventional systemic treatment (e.g., imbruvica). Cutaneous melanoma-approve if the patient has an activating KIT mutation, metastatic or unresectable melanoma, and has tried at least one systemic regimen. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement or an FIP1L1-PDGFR or PDGFRB rearrangement. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Chordoma, desmoid tumors (aggressive fibromatosis), cKit positive metastatic or unresectable cutaneous melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic.  |

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# IMBRUVICA

## Products Affected

- Imbruvica oral capsule
- Imbruvica oral suspension
- Imbruvica oral tablet 420 mg

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | GVHD-1 year and older, other-18 years and older   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | CLL- Approve. GVHD-Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, Jakafi [ruxolitinib tablets]). B-cell lymphoma-approve if the patient has tried at least one systemic regimen (e.g., cisplatin, cytarabine, rituximab, oxaliplatin, gemcitabine, ifosfamide, carboplatin, etoposide, or rituximab). Central nervous system Lymphoma (primary)- approve if the patient is not a candidate for or is intolerant to high-dose methotrexate OR has tried at least one therapy (e.g., methotrexate, rituximab, vincristine, procarbazine, cytarabine, thiotepa, carmustine, intrathecal methotrexate, cytarabine, or rituximab). Hairy Cell Leukemia - approve if the patient has tried at least two systemic regimens (cladribine, Nipent [pentostatin injection], rituximab, or Pegasys [peginterferon alfa-2a subcutaneous injection]). |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma   |
| <b>Part B Prerequisite</b>          | No  |

# INBRIJA

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## Products Affected

- Inbrija inhalation capsule, w/inhalation device

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



# INCRELEX

## Products Affected

- Increlex

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Pediatric patients with closed epiphyses  |
| <b>Required Medical Information</b> | For growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency or growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH, patient meets all of the following prior to beginning therapy with the requested drug (new starts only): 1) height 3 or more standard deviations (SD) below the mean for children of the same age and gender AND 2) basal IGF-1 level 3 or more SD below the mean for children of the same age and gender AND 3) provocative growth hormone test showing a normal or elevated growth hormone level. For growth failure due to severe primary IGF-1 deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH, continuation of therapy: patient is experiencing improvement. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# INGREZZA

## Products Affected

- Ingrezza
- Ingrezza Initiation Pk(tardiv)

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Exclusion Criteria           |                               |
| Required Medical Information | Diagnosis                     |
| Age Restrictions             | 18 years and older            |
| Prescriber Restrictions      |                               |
| Coverage Duration            | 1 year                        |
| Other Criteria               |                               |
| Indications                  | All FDA-approved Indications. |
| Off Label Uses               |                               |
| Part B Prerequisite          | No                            |

# INLYTA

## Products Affected

- Inlyta

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | 18 years and older  |
| Prescriber Restrictions      |   |
| Coverage Duration            | Authorization will be for 1 year  |
| Other Criteria               | Advanced Renal cell carcinoma-approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy. Soft tissue sarcoma-approve if the patient has alveolar soft part sarcoma and the medication will be used in combination with Keytruda (pembrolizumab). |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| Off Label Uses               | Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma, Soft tissue sarcoma  |
| Part B Prerequisite          | No  |

# INQOVI

## Products Affected

- Inqovi

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis  |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| Coverage Duration            | 1 year   |
| Other Criteria               |  |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.     |
| Off Label Uses               | Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Neoplasms |
| Part B Prerequisite          | No   |

# INREBIC

## Products Affected

- Inrebic

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has intermediate-2 or high-risk disease. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis). |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Myeloid/Lymphoid Neoplasms with Eosinophilia, accelerated or blast phase myeloproliferative neoplasm   |
| <b>Part B Prerequisite</b>          | No   |

# ITOVEBI

## Products Affected

- Itovebi

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis  |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| Coverage Duration            | 1 year   |
| Other Criteria               | <p>BREAST CANCER (all of A, B, C, D, E and F): A. Patient meets ONE of the following (i or ii): i. Patient is a postmenopausal female, OR ii. Patient meets BOTH of the following (a and b): a. Patient is a pre/perimenopausal female or a male, AND b. Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist OR had surgical bilateral oophorectomy or ovarian irradiation (female) or orchiectomy (male), Note: Examples of a GnRH agonist include leuprolide acetate, leuprolide acetate intramuscular injection, triptorelin pamoate intramuscular injection, goserelin acetate subcutaneous injection. AND B. Patient has locally advanced or metastatic hormone receptor (HR)-positive disease, AND C. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D. Patient has PIK3CA-mutated breast cancer as detected by an approved test, AND E. Patient meets (i or ii): i) has disease progression while on adjuvant endocrine therapy or ii) had disease recurrence within 12 months after completing adjuvant endocrine therapy, Note: Examples of endocrine therapy include tamoxifen, anastrozole, letrozole, exemestane, toremifene. AND F. The medication will be used in combination with palbociclib capsules/tablets and fulvestrant injection.</p> |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# ITRACONAZOLE

## Products Affected

- itraconazole oral capsule

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | The requested drug will be used orally. For the treatment of onychomycosis due to dermatophytes (Tinea unguium), the diagnosis has been confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy). |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Systemic Fungal infxns: 12 mo. Onychomycosis: (Fingernail) 2 mo. (Toenail) 3 mo.   |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |



# IVERMECTIN (ORAL)

## Products Affected

- ivermectin oral tablet 3 mg

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

# IVIG

## Products Affected

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

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| 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 patient's home. |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |
| Part B Prerequisite          | No  |

# IWILFIN

## Products Affected

- Iwifin

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| 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               |  |
| Part B Prerequisite          | No   |

# JAKAFI

## Products Affected

- Jakafi

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | ALL-1 to 21 years of age, GVHD-12 and older, MF/PV/accelerated or blast phase MPN/CMML-2/essential thrombo/myeloid/lymphoid neoplasm/T-cell Lymphoma-18 and older   |
| Prescriber Restrictions      |   |
| Coverage Duration            | 1 year  |
| Other Criteria               | For polycythemia vera patients must have tried hydroxyurea or peginterferon alfa-2a or Besremi (ropeginterferon alfa-2b-njft subcutaneous injection). ALL-approve if the mutation/pathway is Janus associated kinase (JAK)-related. GVHD, chronic-approve if the patient has tried one conventional systemic treatment for graft versus host disease (for example: prednisone, ibrutinib capsules/tablets). GVHD, acute-approve if the patient has tried one systemic corticosteroid. Atypical chronic myeloid leukemia-approve if the patient has a CSF3R mutation or a janus associated kinase 2 (JAK2) mutation. Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent. Essential thrombocythemia-approve if the patient has tried hydroxyurea, peginterferon alfa-2a or anagrelide. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the tumor has a janus associated kinase 2 (JAK2) rearrangement. T-Cell Lymphoma - approve if pt has (A or B): A) peripheral T-cell lymphoma or B) meets (i and ii): i) pt has T-cell prolymphocytic leukemia, T-cell large granular lymphocytic leukemia, hepatosplenic T-cell lymphoma, or breast implant-associated anaplastic large cell lymphoma and ii) pt has tried at least one systemic regimen. Accelerated or blast phase myeloproliferative neoplasm-approve if pt has at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis). |

| <b>PA Criteria</b>         | <b>Criteria Details</b>   |
|----------------------------|---|
| <b>Indications</b>         | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>      | Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms, T-Cell lymphoma, accelerated or blast phase myeloproliferative neoplasm |
| <b>Part B Prerequisite</b> | No  |

# JAYPIRCA

## Products Affected

- Jaypirca

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

| <b>PA Criteria</b>         | <b>Criteria Details</b>   |
|----------------------------|---|
| <b>Off Label Uses</b>      | Richter's Transformation to Diffuse Large B-Cell Lymphoma, Marginal Zone Lymphoma |
| <b>Part B Prerequisite</b> | No  |

# KALYDECO

## Products Affected

- Kalydeco

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Combination use with Orkambi, Trikafta or Symdeko   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | 1 month of age and older  |
| <b>Prescriber Restrictions</b>      | prescribed by or in consultation with a pulmonologist or a physician who specializes in CF  |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | CF - must meet A, B, and C: A) pt must have one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |



# KETOCONAZOLE

## Products Affected

- ketoconazole oral

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Acute or chronic liver disease. Concurrent use with drugs that are contraindicated with ketoconazole tablets: dofetilide, quinidine, pimozide, cisapride, methadone, disopyramide, dronedarone, ranolazine, ergot alkaloids, irinotecan, lurasidone, oral midazolam, alprazolam, triazolam, felodipine, nisoldipine, tolvaptan, eplerenone, lovastatin, simvastatin, or colchicine.                          |
| <b>Required Medical Information</b> | The potential benefits outweigh the risks of treatment with oral ketoconazole. For systemic fungal infections, the patient has any of the following diagnoses: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis. For Cushing's syndrome: the requested drug is being prescribed for a patient who cannot tolerate surgery or where surgery has not been curative. |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 6 months   |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Cushing's syndrome   |
| <b>Part B Prerequisite</b>          | No   |

# KEYTRUDA

## Products Affected

- Keytruda

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 and older (except Merkel cell, MSI-H/dMMR tumors, large B-cell lymph, TMB-H, glioma) Glioma - less than 18 years old   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | Adjuvant treatment of melanoma/RCC-approve up to 1 year total, all other dx-1 year  |
| <b>Other Criteria</b>               | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.   |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | 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 |
| <b>Part B Prerequisite</b>          | No  |

# KISQALI

## Products Affected

- Kisqali
- Kisqali Femara Co-Pack

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | 18 years and older  |
| Prescriber Restrictions      |   |
| Coverage Duration            | 1 year  |
| Other Criteria               | <p>Breast cancer - approve for hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative early (stage II or III), recurrent, or metastatic breast cancer [for early breast cancer must be adjuvant treatment and high risk of recurrence] when the pt meets ONE of the following</p> <ol style="list-style-type: none"> <li>1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole</li> <li>2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, or letrozole</li> <li>3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Kisqali will be used in combination with anastrozole, exemestane or letrozole.</li> <li>4. Patient is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole.</li> </ol> <p>Endometrial cancer - approve if pt meets all of (A, 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.</p> |

| <b>PA Criteria</b>             | <b>Criteria Details</b>  |
|--------------------------------|--|
| <b>Indications</b>             | All FDA-approved Indications, Some Medically-accepted Indications. |
| <b>Off Label Uses</b>          | Endometrial cancer   |
| <b>Part B<br/>Prerequisite</b> | No   |

# KORLYM

## Products Affected

- Korlym
- mifepristone oral tablet 300 mg

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis, prior surgeries   |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome   |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | Endogenous Cushing's Syndrome-Approve if mifepristone is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance AND pt meets (i, ii or iii): i) patient is not a candidate for surgery or surgery has not been curative, or (ii) patient is awaiting surgery for endogenous Cushing's Syndrome or (iii) patient is awaiting therapeutic response after radiotherapy for endogenous Cushing's Syndrome. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# KOSELUGO

## Products Affected

- Koselugo

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | 1 year  |
| Other Criteria               | <p>Neurofibromatosis Type 1-approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas and if the patient is 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 lesions, OR iv. Patient has central nervous system disease, AND B) The medication is used as a single agent.</p> |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| Off Label Uses               | Circumscribed Glioma, Langerhans Cell Histiocytosis   |

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# KRAZATI

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## Products Affected

- Krazati

| PA Criteria                  | Criteria Details   |
|------------------------------|--------------------|
| Exclusion Criteria           |                    |
| Required Medical Information | Diagnosis          |
| Age Restrictions             | 18 years and older |
| Prescriber Restrictions      |                    |
| Coverage Duration            | 1 year             |



| PA Criteria                | Criteria Details  |
|----------------------------|---|
| <b>Other Criteria</b>      | <p>Non-Small Cell Lung Cancer (NSCLC)-approve if (A and B): A) the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND B) patient meets either (i or ii): i) has been previously treated with at least one systemic regimen [Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine.] or ii) patient has brain metastases. Colon or Rectal Cancer- approve if pt has unresectable, advanced, or metastatic disease AND pt has KRAS G12C mutation-positive disease AND medication is prescribed as part of a combination regimen or the patient is unable to tolerate combination therapy AND pt has has previously received a chemotherapy regimen for colon or rectal cancer. Ampullary adenocarcinoma-approve if (A, B and C): A) metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy. Biliary tract cancer- approve if (A, B and C): A) unresectable or metastatic disease, B) KRAS G12C mutation-positive disease, and C) previously treated with at least one systemic regimen. Pancreatic adenocarcinoma- approve if (A and B): A) KRAS G12C mutation-positive disease, and B) either (i or ii): (i) locally advanced or metastatic disease and previously treated with at least one systemic regimen, or (ii) recurrent disease after resection. Small bowel adenocarcinoma- approve if (A, B and C): A) advanced or metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy.</p> |
| <b>Indications</b>         | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>      | Ampullary adenocarcinoma, biliary tract cancer, pancreatic adenocarcinoma, small bowel adenocarcinoma   |
| <b>Part B Prerequisite</b> | No  |

# LANREOTIDE

## Products Affected

- lanreotide subcutaneous syringe 120 mg/0.5 mL
- Somatuline Depot subcutaneous syringe 60 mg/0.2 mL, 90 mg/0.3 mL

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis, previous treatments/therapies  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.<br>Pheochromocytoma/paraganglioma-prescribed by or in consultation with an endo/onc/neuro.   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Acromegaly-approve if the patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii:<br>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).<br>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.<br>Carcinoid Syndrome-approve. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Pheochromocytoma/paraganglioma  |
| <b>Part B Prerequisite</b>          | No  |

# LAPATINIB

## Products Affected

- lapatinib

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

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | Yes              |

# LAZCLUZE

## Products Affected

- Lazcluze

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             | 18 years and older  |
| Prescriber Restrictions      |   |
| Coverage Duration            | 1 year  |
| Other Criteria               | NON-SMALL CELL LUNG CANCER-ALL of the following (A, B, C, and D): A. Locally advanced or metastatic disease, AND B. Epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test, AND C. Used in combination with Rybrevant, AND D. Used as first-line treatment. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |
| Part B Prerequisite          | No  |

# LEDIPASVIR/SOFOSBUVIR

## Products Affected

- ledipasvir-sofosbuvir

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

# LENALIDOMIDE

## Products Affected

- lenalidomide
- Revlimid

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis and previous therapies or drug regimens tried.  |
| <b>Age Restrictions</b>             | 18 years and older (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma)   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Authorization will be for 1 year  |
| <b>Other Criteria</b>               | <p>Follicular lymphoma-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one prior therapy. MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one other therapy or therapeutic regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). B-cell-lymphoma (other)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve. CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-approve if the patient has tried at least three other regimens. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide is used in combination with dexamethasone. Histiocytic neoplasms-approve if the patient has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman disease.</p> |

| <b>PA Criteria</b>         | <b>Criteria Details</b>   |
|----------------------------|---|
| <b>Indications</b>         | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>      | Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system Lymphoma, Kaposi's sarcoma, histiocytic neoplasms. |
| <b>Part B Prerequisite</b> | No  |



# LENVIMA

## Products Affected

- Lenvima

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| Coverage Duration            | 1 year   |
| Other Criteria               | <p>DTC - must be refractory to radioactive iodine treatment for approval. RCC - approve if the pt meets ALL of the following criteria: 1) pt has advanced disease AND if the patient meets i or ii-i. Lenvima is is being used in combination with Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b-a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that is mismatch repair proficient (pMMR) or not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND B) The medication is used in combination with Keytruda (pembrolizumab for intravenous injection) AND C)the disease has progressed on at least one prior systemic therapy AND D) The patient is not a candidate for curative surgery or radiation. HCC-approve if the patient has unresectable or metastatic disease. Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. Melanoma - approve if the patient has unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy. Anaplastic thyroid carcinoma-approve if the medication is used in combination with Keytruda (pembrolizumab intravenous infusion).</p> |

| <b>PA Criteria</b>             | <b>Criteria Details</b>   |
|--------------------------------|---|
| <b>Indications</b>             | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>          | Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Melanoma, Anaplastic thyroid carcinoma |
| <b>Part B<br/>Prerequisite</b> | No  |

# LIBERVANT

## Products Affected

- Libervant

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Exclusion Criteria           |                               |
| Required Medical Information | Diagnosis                     |
| Age Restrictions             | 2 to 5 years of age           |
| Prescriber Restrictions      |                               |
| Coverage Duration            | 1 year                        |
| Other Criteria               |                               |
| Indications                  | All FDA-approved Indications. |
| Off Label Uses               |                               |
| Part B Prerequisite          | No                            |

# LIDOCAINE PATCH

## Products Affected

- DermacinRx Lidocan
- lidocaine topical adhesive patch,medicated 5 %
- Lidocan III
- Lidocan IV
- Lidocan V
- Tridacaine
- Tridacaine II

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

# LIVTENCITY

## Products Affected

- Livtencity

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

# LONG ACTING OPIOIDS

## Products Affected

- Methadone Intensol
- methadone oral concentrate
- methadone oral solution
- methadone oral tablet
- morphine oral tablet extended release

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Acute (ie, non-chronic) pain   |
| <b>Required Medical Information</b> | Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.   |
| <b>Other Criteria</b>               | For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, in hospice, sickle cell disease or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# LONSURF

## Products Affected

- Lonsurf

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Authorization will be for 1 year   |
| Other Criteria               | Gastric or Gastroesophageal Junction Adenocarcinoma, approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma. Colon and rectal cancer-approve per labeling if the patient has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type), they must also try an anti-EGFR therapy. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |
| Part B Prerequisite          | No   |

# LORBRENA

## Products Affected

- Lorbrena

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



# LUMAKRAS

## Products Affected

- Lumakras

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Authorization will be for 1 year   |
| <b>Other Criteria</b>               | <p>Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Ampullary adenocarcinoma - approve if pt has KRAS G12C-mutated disease as determined by an approved test AND this is used as subsequent therapy. Colon or rectal cancer - approve if pt meets all (A, B, C and D): A) unresectable, advanced, or metastatic disease, and B) KRAS G12C mutation-positive disease, and C) medication is prescribed as part of a combination regimen for colon or rectal cancer [Ex: Lumakras plus cetuximab or panitumumab] or patient is unable to tolerate combination therapy, and D) previously received a chemotherapy regimen for colon or rectal cancer. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease, as determined by an approved test AND either (i or ii): (i) patient has locally advanced or metastatic disease and has been previously treated with at least one systemic regimen OR (ii) patient has recurrent disease after resection.</p> |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma  |
| <b>Part B Prerequisite</b>          | No   |

# LUMIZYME

## Products Affected

- Lumizyme

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

# LUPRON DEPOT

## Products Affected

- Lupron Depot

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

| PA Criteria                | Criteria Details  |
|----------------------------|---|
| <b>Off Label Uses</b>      | abnormal uterine bleeding, breast cancer, gender dysphoria/gender reassignment, head and neck cancer-salivary gland tumors, ovarian cancer including fallopian tube and primary peritoneal cancers, premenstrual disorders including premenstrual syndrome and premenstrual dysphoric disorder, prophylaxis or treatment of uterine bleeding or menstrual suppression in pts with hematologic malignancy or undergoing cancer treatment or prior to bone marrow or stem cell transplant, uterine cancer |
| <b>Part B Prerequisite</b> | No  |

# LYNPARZA

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## Products Affected

- Lynparza

| PA Criteria                  | Criteria Details   |
|------------------------------|--------------------|
| Exclusion Criteria           |                    |
| Required Medical Information |                    |
| Age Restrictions             | 18 years and older |
| Prescriber Restrictions      |                    |
| Coverage Duration            | 1 year             |

| PA Criteria                | Criteria Details   |
|----------------------------|--|
| <b>Other Criteria</b>      | <p>Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND The patient is in complete or partial response to at least one platinum-based chemotherapy regimen (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has recurrent or metastatic disease and has (i or ii): i) germline BRCA mutation-positive breast cancer or ii) germline PALB2 mutation-positive breast cancer. Pancreatic Cancer-maintenance therapy-approve if the patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate cancer-castration resistant-approve if the patient has metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or the patient has had a bilateral orchiectomy, and the patient meets either (i or ii): i) the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test and the patient has been previously treated with at least one androgen receptor directed therapy or ii) the patient has a BRCA mutation and the medication is used in combination with abiraterone plus one of prednisone or prednisolone. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried at least one systemic regimen.</p> |
| <b>Indications</b>         | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>      | Uterine Leiomyosarcoma   |
| <b>Part B Prerequisite</b> | No   |

# LYTGOBI

## Products Affected

- Lytgobi oral tablet 12 mg/day (4 mg x 3), 16 mg/day (4 mg x 4), 20 mg/day (4 mg x 5)

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             | 18 years and older  |
| Prescriber Restrictions      |   |
| 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               |   |
| 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)

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



# MEKINIST

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## Products Affected

- Mekinist

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| 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      |   |
| Coverage Duration            | Authorization will be for 1 year  |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>Melanoma must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC requires BRAF V600E Mutation and use in combination with Tafenlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafenlar, unless intolerant AND the patient has BRAF V600-positive disease. Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for low-grade serous carcinoma or the patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or 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 Tafenlar (dabrafenib). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR patient has Erdheim Chester disease or Rosai-Dorfman disease. Metastatic or Solid Tumors-Approve if the patient meets the following (A, B, and C): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafenlar (dabrafenib capsules), AND C) Patient has no satisfactory alternative treatment options. Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Tafenlar. Small bowel adenocarcinoma, approve if pt has BRAF V600E mutation-positive advanced or metastatic disease and this will be used with Tafenlar AND</p> |
|                       | (i or ii): i) this will be used as initial therapy and pt has received previous FOLFOX/CAPEOX therapy in the adjuvant setting within the past 12 months or has a contraindication, or (ii) this will be used as second-line and subsequent therapy.  |
| <b>Indications</b>    | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b> | Histiocytic Neoplasm, Hairy Cell Leukemia  |

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# MEKTOVI

## Products Affected

- Mektovi

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

# MEMANTINE

## Products Affected

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

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Indication for which memantine is being prescribed.                                      |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Authorization will be for 12 months.   |
| Other Criteria               | This Prior Authorization requirement only applies to patients 26 years of age or younger |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.                       |
| Off Label Uses               | Patients with mild to moderate vascular dementia.  |
| Part B Prerequisite          | No   |

# MODAFINIL/ARMODAFINIL

## Products Affected

- armodafinil
- modafinil

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

# MONJUVI

## Products Affected

- Monjuvi

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-Cell Lymphoma - Approve if the patient 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. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# NAGLAZYME

## Products Affected

- Naglazyme

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



# NAYZILAM

## Products Affected

- Nayzilam

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

# NERLYNX

## Products Affected

- Nerlynx

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

# NINLARO

## Products Affected

- Ninlaro

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

# NITISINONE

## Products Affected

- nitisinone

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

# NIVESTYM

## Products Affected

- Nivestym

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Cancer/AML, MDS, ALL-oncologist or a hematologist. Cancer patients receiving BMT and PBPC-prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation. SCN-hematologist. HIV/AIDS neutropenia-infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.  |
| <b>Coverage Duration</b>            | chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT, Radiation-1 mo  |
| <b>Other Criteria</b>               | Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 2)patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), 3)patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm <sup>3</sup> ], neutropenia expected to be greater than 10 days in duration, invasive fungal infection). |

| <b>PA Criteria</b>         | <b>Criteria Details</b>   |
|----------------------------|---|
| <b>Indications</b>         | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>      | Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Acute lymphocytic leukemia (ALL), Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome) |
| <b>Part B Prerequisite</b> | No  |

# NON-INJECTABLE TESTOSTERONE PRODUCTS

## Products Affected

- testosterone transdermal gel
- testosterone transdermal gel in metered-dose pump 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)

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

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



# NUBEQA

## Products Affected

- Nubeqa

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (See Note 1) or if the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration sensitive-approve if the medication will be used in combination with a GnRH analog (See Note 1) or if the patient had a bilateral orchiectomy. Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets). |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# NUDEXTA

## Products Affected

- Nuedexta

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

# NUPLAZID

## Products Affected

- Nuplazid

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

# NURTEC

## Products Affected

- Nurtec ODT

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention if Nurtec ODT is being taking for the preventive treatment of episodic migraine.   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Migraine, Acute treatment (initial and continuation)-approve. Preventive treatment of episodic migraine (initial)-approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication). Preventive treatment of episodic migraine (continuation) - approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication) and the patient has had a significant clinical benefit from the medication. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# NYVEPRIA

## Products Affected

- Nyvepria

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.  |
| <b>Coverage Duration</b>            | Cancer pts receiving chemo-6 mo. PBPC-1 mo   |
| <b>Other Criteria</b>               | Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 2) patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, or 3) patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Patients undergoing PBPC collection and therapy  |
| <b>Part B Prerequisite</b>          | No   |

# OCALIVA

## Products Affected

- Ocaliva

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Prescriber specialty, lab values, prior medications used for diagnosis and length of trials  |
| <b>Age Restrictions</b>             | 18 years and older (initial)   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)  |
| <b>Coverage Duration</b>            | 6 months initial, 1 year cont.   |
| <b>Other Criteria</b>               | 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. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# OCREVUS

## Products Affected

- Ocrevus

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

# OCTREOTIDE INJECTABLE

## Products Affected

- octreotide acetate

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis  |
| Age Restrictions             |  |
| Prescriber Restrictions      | Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-prescr/consult with oncologist. Diarrhea assoc w chemo-prescr/consult with oncologist/gastro.  |
| Coverage Duration            | Enterocutaneous fistula/diarrhea assoc w chemo - 3 months, all others - 1 year   |
| Other Criteria               | ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender. DIARRHEA ASSOC W CHEMO (A and B): A) grade 3 or 4 diarrhea and B) patient has tried at least one antimotility medication. |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| Off Label Uses               | Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma, enterocutaneous fistulas, diarrhea associated with chemotherapy  |
| Part B Prerequisite          | No   |



# ODOMZO

## Products Affected

- Odomzo

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | BCC - Must not have had disease progression while on Erivedge (vismodegib).   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metastatic BCC - approve, if the disease is limited to nodal metastases. (Note-This includes primary or recurrent nodal metastases. A patient with distant metastasis does not meet this requirement.) Diffuse Basal Cell Carcinoma Formation, including basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma - approve. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Metastatic BCC, diffuse basal cell carcinoma formation  |
| <b>Part B Prerequisite</b>          | No  |

# OFEV

## Products Affected

- Ofev

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | 18 years of age and older  |
| Prescriber Restrictions      | IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.   |
| Coverage Duration            | 1 year   |
| Other Criteria               | IDIOPATHIC PULMONARY FIBROSIS (IPF), INITIAL [A and B]: A) diagnosis confirmed by presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) or surgical lung biopsy and B) forced vital capacity (FVC) greater than or equal to 40 percent of the predicted value. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS, INITIAL (A and B): A) diagnosis confirmed by HRCT and B) FVC greater than or equal to 40 percent of the predicted value. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE, INITIAL (all of A, B and C): A) FVC greater than or equal to 45 percent of the predicted value, B) fibrosing lung disease impacting more than 10 percent of lung volume on HRCT, and C) clinical signs of progression. ALL INDICATIONS, CONTINUATION: approve. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |
| Part B Prerequisite          | No   |

# OGSIVEO

## Products Affected

- Ogsiveo

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             | 18 years and older  |
| Prescriber Restrictions      |   |
| Coverage Duration            | 1 year  |
| Other Criteria               | Desmoid tumors (aggressive fibromatosis)-approve if the patient has progressing desmoid tumors, the desmoid tumors are not amenable to surgery or radiotherapy and if the patient requires systemic treatment. Note: Progressing desmoid tumors are defined as greater than or equal to 20 percent progression within 12 months |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |
| Part B Prerequisite          | No  |

# OJEMDA

## Products Affected

- Ojemda

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis  |
| Age Restrictions             | 6 months of age and older  |
| Prescriber Restrictions      |  |
| Coverage Duration            | 1 year   |
| Other Criteria               | PEDIATRIC LOW GRADE GLIOMA-patient has relapsed or refractory disease and the tumor is positive for one of the following: BRAF fusion, BRAF rearrangement or BRAF V600 mutation. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |
| Part B Prerequisite          | No   |

# OJJAARA

## Products Affected

- Ojjaara

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 years of age and older   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Myelofibrosis-approve if the patient has (A, B or C): A) intermediate-risk or high-risk disease, or B) lower-risk disease and has one disease-related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis), or C) myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease- related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis). |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Accelerated or blast phase myeloproliferative neoplasm  |
| <b>Part B Prerequisite</b>          | No  |

# OMNIPOD

## Products Affected

- Omnipod 5 G6-G7 Intro Kit(Gen5)
- Omnipod 5 G6-G7 Pods (Gen 5)
- Omnipod Dash Intro Kit (Gen 4)
- Omnipod Dash Pods (Gen 4)

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Initial: 1) The patient has diabetes requiring insulin management with multiple daily injections AND 2) The patient is self-testing glucose levels 2 or more times per day OR the patient is using a continuous glucose monitor AND 3) For patients with Type 2 diabetes: The patient has a history of problematic hypoglycemia defined as 1) Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan OR 2) A history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia. Continuation: the patient has stable or improved glycemic control. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# ONUREG

## Products Affected

- Onureg

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | AML - Approve if the medication is used for post-remission maintenance therapy AND allogeneic hematopoietic stem cell transplant is not planned. Peripheral T-cell lymphoma - all of (A, B, and C): A) relapsed or refractory disease, and B) pt has one of the following (i, ii or iii): i) angioimmunoblastic T-cell lymphoma, or ii) nodal peripheral T-cell lymphoma with T-follicular helper (TFH) phenotype, or iii) follicular T-cell lymphoma, and C) medication is used as a single agent. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Peripheral T-cell lymphoma  |
| <b>Part B Prerequisite</b>          | No  |

# OPSUMIT

## Products Affected

- Opsumit

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | PAH WHO group, right heart catheterization results  |
| Age Restrictions             |   |
| 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               |   |
| Part B Prerequisite          | No  |



# ORGOVYX

## Products Affected

- Orgovyx

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Exclusion Criteria           |                               |
| Required Medical Information | Diagnosis                     |
| Age Restrictions             | 18 years and older            |
| Prescriber Restrictions      |                               |
| Coverage Duration            | 1 year                        |
| Other Criteria               | Prostate Cancer-approve.      |
| Indications                  | All FDA-approved Indications. |
| Off Label Uses               |                               |
| Part B Prerequisite          | No                            |

# ORKAMBI

## Products Affected

- Orkambi

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Combination use with Kalydeco, Trikafta or Symdeko.  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | 1 year of age and older  |
| <b>Prescriber Restrictions</b>      | prescribed by or in consultation with a pulmonologist or a physician who specializes in CF   |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | CF - Approve if the pt meets A, B and C: A) pt has two copies of the F508del mutation in the CTFR gene, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# ORSERDU

## Products Affected

- Orserdu

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

# OTEZLA

## Products Affected

- Otezla
- Otezla Starter oral tablets,dose pack 10 mg (4)-20 mg (51), 10 mg (4)-20 mg (4)-30 mg (47)

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

# OXERVATE

## Products Affected

- Oxervate

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Treatment duration greater than 16 weeks per affected eye(s)  |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by an ophthalmologist or an optometrist.   |
| <b>Coverage Duration</b>            | Initial-8 weeks, continuation-approve for an additional 8 weeks   |
| <b>Other Criteria</b>               | Patient has Stage 2 or higher neurotrophic keratitis. Patients who have already received Oxervate-approve if the patient has previously received less than or equal to 8 weeks of treatment per affected eye(s) and the patient has a recurrence of neurotrophic keratitis. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# PANRETIN

## Products Affected

- Panretin

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             |   |
| 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               |   |
| Part B Prerequisite          | No  |

# PEGASYS

## Products Affected

- Pegasys

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | HBV 48wks. Other Plan Yr  |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis), systemic mastocytosis, adult T-cell leukemia/lymphoma, mycosis fungoides/sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders, hairy cell leukemia, Erdheim-Chester disease. |
| <b>Part B Prerequisite</b>          | No  |

# PEMAZYRE

## Products Affected

- Pemazyre

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis, prior therapies   |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| 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               |  |
| Part B Prerequisite          | No   |



# PHENYLBUTYRATE

## Products Affected

- sodium phenylbutyrate

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

# PHEOCHROMOCYTOMA

## Products Affected

- metyrosine

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

# PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

## Products Affected

- Alyq
- sildenafil (pulm.hypertension) oral tablet
- tadalafil (pulm. hypertension)

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

# PIQRAY

## Products Affected

- Piqray

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

# PIRFENIDONE

## Products Affected

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

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

# POMALYST

## Products Affected

- Pomalyst

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

# POSACONAZOLE (ORAL)

## Products Affected

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

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | Aspergillus/Candida prophylaxis, mucormycosis-6 mo, all others-3 months   |
| Other Criteria               |   |
| 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  |

# PRALUENT

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## Products Affected

- Praluent Pen

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | Concurrent use of Leqvio or Repatha.  |
| Required Medical Information | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field) |
| Age Restrictions             | HeFH - 8 years and older. All other - 18 years of age and older.  |
| Prescriber Restrictions      |   |
| Coverage Duration            | Authorization will be for 1 year  |



| PA Criteria         | Criteria Details  |
|---------------------|---|
| Other Criteria      | <p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL (or 155 mg/dL if less than 16 years old), b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD, HeFH, or HoFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. HYPERLIPIDEMIA WITH HoFH (both A and B): A) meets (a or b): a) phenotypic confirmation of HoFH, or b) meets (i and ii): i) untreated LDL-C greater than 400 mg/dL or treated LDL-C greater than or equal to 300 mg/dL, and ii) clinical manifestations of HoFH before 10 years of age or at least one parent with untreated LDL-C or total cholesterol consistent with FH, AND B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 70 mg/dL or higher or b) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.</p> |
| Indications         | All FDA-approved Indications.   |
| Off Label Uses      |   |
| Part B Prerequisite | No  |

# PREVYMIS

## Products Affected

- Prevymis oral tablet

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | For prophylaxis of cytomegalovirus (CMV) infection or disease in allogeneic hematopoietic stem cell transplant (HSCT) recipients: 1) the patient is CMV-seropositive, AND 2) the requested drug will not be used beyond day 100 post-transplantation. For prophylaxis of CMV disease in kidney transplant recipients: 1) the donor is CMV seropositive (D+), 2) the patient/recipient is CMV seronegative (R-), AND 3) the requested drug will not be used beyond day 200 post-transplantation. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 6 months  |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# PROMACTA

## Products Affected

- Promacta

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts.   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Immune Thrombocytopenia or Aplastic Anemia, prescribed by, or after consultation with, a hematologist (initial therapy). Hep C, prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease (initial therapy). MDS-presc or after consult with heme/onc (initial therapy). Post-transplant, prescribed by or in consult with a hematologist, oncologist or stem cell transplant specialist physician (initial) |
| <b>Coverage Duration</b>            | ImmuneThrombo/MDS<br>init3mo,cont1yr,AAinit4mo,cont1yr,Thrombo/HepC1yr,Transplant-<br>init3mo,cont6mo  |

| PA Criteria                | Criteria Details   |
|----------------------------|--|
| <b>Other Criteria</b>      | <p>Thrombocytopenia in patients with immune thrombocytopenia, initial-approve if the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate, Tavalisse, Doptelet, rituximab) or has undergone a splenectomy. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.</p> <p>Treatment of thrombocytopenia in patients with Chronic Hepatitis C initial - approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND if the patient has low platelet counts at baseline (eg, less than 75,000 microliters). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000 microliter) AND tried one immunosuppressant therapy (e.g., cyclosporine) OR patient will be using Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response.</p> <p>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.</p> <p>Thrombocytopenia post-allogeneic transplantation, initial - approve if, according to the prescriber, the patient has poor graft function AND has a platelet count less than 50,000/mcL. Cont- patient demonstrated a beneficial clinical response.</p> |
| <b>Indications</b>         | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>      | Thrombocytopenia in Myelodysplastic Syndrome (MDS), Thrombocytopenia in a patient post-allogeneic transplantation  |
| <b>Part B Prerequisite</b> | No   |

# PYRIMETHAMINE

## Products Affected

- pyrimethamine

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

# QINLOCK

## Products Affected

- Qinlock

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

# QUININE SULFATE

## Products Affected

- quinine sulfate

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | For babesiosis: the requested drug is prescribed in combination with clindamycin  |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | 1 month   |
| Other Criteria               | Chloroquine-sensitive Plasmodium falciparum malaria: Failure, contraindication or intolerance to chloroquine or hydroxychloroquine. |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| Off Label Uses               | Babesiosis, uncomplicated Plasmodium vivax malaria.   |
| Part B Prerequisite          | No  |

# RADICAVA ORS

## Products Affected

- Radicava ORS
- Radicava ORS Starter Kit Susp

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | ALSFRS-R score   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS (initial and continuation).   |
| <b>Coverage Duration</b>            | Initial, 6 months. Continuation, 6 months  |
| <b>Other Criteria</b>               | ALS, initial therapy - approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, based on the application of the El Escorial or the revised Airline house diagnostic criteria AND 2. Patient has a score of two points or more on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. Patient has adequate respiratory function according to the prescriber, AND 4. Patient has received or is currently receiving riluzole tablets. Note-a trial of Tiglutik or Exservan would also count. ALS, continuation therapy - approve if, according to the prescribing physician, the patient continues to benefit from therapy. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |



# REMICADE

## Products Affected

- Inflectra

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent use with Biologic DMARD or Targeted Synthetic DMARD  |
| <b>Required Medical Information</b> | Diagnosis, concurrent medication, previous medications tried  |
| <b>Age Restrictions</b>             | CD and UC, Pts aged 6 years or more (initial therapy). PP-18 years and older (initial therapy)  |
| <b>Prescriber Restrictions</b>      | All dx-initial therapy only-Prescribed by or in consult w/RA/AS/Still's/JIA/JRA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's- rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarcoidosis-pulmonol, ophthalmol, or dermatol, cardio/neuro. |
| <b>Coverage Duration</b>            | FDAind ini-3 mo,cont1yr,GVHD ini-1 mo,cont-3 mo,Pyo Gang-ini4 mo,cont1 yr,others-ini 3mo,cont-12 mo   |

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

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

# REMODULIN

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## 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             |  |
| 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   |

| PA Criteria                | Criteria Details   |
|----------------------------|--|
| <b>Other Criteria</b>      | <p>Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Pulmonary Arterial Hypertension (PAH) [World Health Organization (WHO) Group 1], Initial Therapy-Approve if the patient meets all of the following criteria (i, ii, iii, and iv): i. Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH), AND ii. Patient meets the following criteria (a and b): a) Patient has had a right heart catheterization, AND b) Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH, AND iii. Patient meets ONE of the following criteria (a or b): a) Patient is in Functional Class III or IV, OR b) Patient is in Functional Class II and meets ONE of the following criteria [(1) or (2)]: (1) Patient has tried or is currently receiving one oral agent for PAH, OR (2) Patient has tried one inhaled or parenteral prostacyclin product for PAH, AND iv. Patient with idiopathic PAH must meet ONE of the following criteria (a, b, c, d, or e): a) Patient meets both of the following criteria [(1) and (2)]: (1) the patient has had an acute response to vasodilator testing that occurred during the right heart catheterization, AND (2) Patient has tried one calcium channel blocker (CCB) therapy, OR b) According to the prescriber, the patient did not have an acute response to vasodilator testing, OR c) 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.</p> |
| <b>Indications</b>         | All FDA-approved Indications.  |
| <b>Off Label Uses</b>      |  |
| <b>Part B Prerequisite</b> | No   |

# RETEVMO

## Products Affected

- Retevmo

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors-2 years and older, all others 18 years and older   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Authorization will be for 1 year  |
| <b>Other Criteria</b>               | Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has recurrent, advanced or metastatic disease AND the tumor is RET fusion-positive. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion positive or RET mutation positive disease or RET pathogenic variant AND the patient meets i 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. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Anaplastic thyroid carcinoma, histiocytic neoplasm  |
| <b>Part B Prerequisite</b>          | No  |

# REVUFORJ

## Products Affected

- Revuforj

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

# REZLIDHIA

## Products Affected

- Rezlidhia

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             | 18 years and older  |
| Prescriber Restrictions      |   |
| 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               |   |
| Part B Prerequisite          | No  |



# REZUROCK

## Products Affected

- Rezurock

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             | 12 years and older  |
| Prescriber Restrictions      |   |
| 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               |   |
| Part B Prerequisite          | No  |

# RINVOQ

## Products Affected

- Rinvoq

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent use with a biologic or with a targeted synthetic DMARD, Concurrent use with other potent immunosuppressants, Concurrent use with an anti-interleukin monoclonal antibody, Concurrent use with other janus kinase inhibitors, or concurrent use with a biologic immunomodulator.  |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous drugs tried.  |
| <b>Age Restrictions</b>             | PsA/JIA - 2 years and older (initial therapy), RA/UC/AS/CD/nr-axSpA/GCA-18 years and older (initial therapy), AD-12 years and older (initial therapy)   |
| <b>Prescriber Restrictions</b>      | RA/AS/Non-Radiographic Spondy/JIA/GCA, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or dermatologist. UC/CD-prescribed by or in consultation with a gastroenterologist. (all apply to initial therapy only)  |
| <b>Coverage Duration</b>            | Approve through end of plan year  |
| <b>Other Criteria</b>               | INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA)/PSORIATIC ARTHRITIS (PsA)/ULCERATIVE COLITIS (UC)/ANKYLOSING SPONDYLITIS (AS)/CROHN'S DISEASE (CD)/ JUVENILE IDIOPATHIC ARTHRITIS (JIA): 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. ATOPIC DERMATITIS (AD): 4-month trial of at least one systemic therapy (e.g., Dupixent [dupilumab subcutaneous injection] and Adbry [tralokinumab-ldrm subcutaneous injection]. Azathioprine, cyclosporine, or mycophenolate mofetil also count.) or unable to tolerate a 4-month trial. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (A and B): A) objective signs of inflammation defined as having at least one of the following (a or b): a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI and B) 3-month trial of at least one TNFi or was unable to tolerate a 3-month trial. GIANT CELL ARTERITIS: tried one systemic corticosteroid. CONTINUATION THERAPY: ALL INDICATIONS: patient responded to therapy. |
| <b>Indications</b>                  | All FDA-approved Indications.   |

| <b>PA Criteria</b>             | <b>Criteria Details</b> |
|--------------------------------|-------------------------|
| <b>Off Label Uses</b>          |                         |
| <b>Part B<br/>Prerequisite</b> | No                      |

# RINVOQ LQ

## Products Affected

- Rinvoq LQ

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

# ROMVIMZA

## Products Affected

- Romvimza

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             | 18 years and older  |
| Prescriber Restrictions      |   |
| Coverage Duration            | 1 year  |
| Other Criteria               | TENOSYNOVIAL GIANT CELL TUMOR (PIGMENTED VILLONODULAR SYNOVITIS)-tumor is not amenable to improvement with surgery. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |
| Part B Prerequisite          | No  |

# ROZLYTREK

## Products Affected

- Rozlytrek

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

# RUBRACA

## Products Affected

- Rubraca

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer- Approve if the patient is in complete or partial response after a platinum-based chemotherapy regimen and the patient is in complete or partial response to first-line primary treatment or if the patient has recurrent disease and has a BRCA mutation. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B and C): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy. Pancreatic adenocarcinoma- approve if pt has a BRCA mutation or PALB2 mutation AND pt has tried platinum-based chemotherapy AND has not had disease progression following the most recent platinum-based chemotherapy. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma  |
| <b>Part B Prerequisite</b>          | No   |

# RUFINAMIDE

## Products Affected

- rufinamide

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



# RUXIENCE

## Products Affected

- Ruxience

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| 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               |   |
| Part B Prerequisite          | No  |

# RYDAPT

## Products Affected

- Rydapt

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

# SAPROPTERIN

## Products Affected

- sapropterin

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent use with Palynziq  |
| <b>Required Medical Information</b> | Diagnosis, Phe concentration  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)   |
| <b>Coverage Duration</b>            | Initial-12 weeks, Continuation-1 year   |
| <b>Other Criteria</b>               | Initial - approve. Continuation (Note-if the patient has received less than 12 weeks of therapy or is restarting therapy with sapropterin should be reviewed under initial therapy) - approve if the patient has had a response to therapy. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# SCSEMBLIX

## Products Affected

- Scemblix

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

# SIGNIFOR

## Products Affected

- Signifor

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

# SIRTURO

## Products Affected

- Sirturo

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

# SKYRIZI

## Products Affected

- Skyrizi

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)  |
| <b>Required Medical Information</b> | Diagnosis, Previous medication use  |
| <b>Age Restrictions</b>             | PP/UC-18 years of age and older (initial therapy)   |
| <b>Prescriber Restrictions</b>      | PP-Prescribed by or in consultation with a dermatologist (initial therapy), PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy), CD/UC-presc/consult-gastro (initial therapy) |
| <b>Coverage Duration</b>            | Approve through end of plan year  |

| PA Criteria                | Criteria Details   |
|----------------------------|--|
| <b>Other Criteria</b>      | <p>INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or PUVA) for at least 3 months, unless intolerant. (Note: a 3-month trial or previous intolerance to at least one biologic also counts) or B) contraindication to MTX. PSORIATIC ARTHRITIS (PsA): approve. CROHN'S DISEASE (CD) [one of A, B, C, or D]: A) tried or is currently taking corticosteroids, unless contraindicated, B) tried one other conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine, MTX) [Notes: a trial of a biologic that is not a biosimilar of Skyrizi also counts. A trial of mesalamine does not count as a systemic agent], C) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, or D) patient had ileocolonic resection to reduce the chance of CD recurrence. UICERATIVE COLITIS (UC)-meets ONE of the following (a or b): a)Patient has had a trial of one systemic agent for ulcerative colitis, Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. OR b)Patient meets BOTH of the following [(1) and (2)]: (1)Patient has pouchitis, AND (2)Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema. CD/UC: Patient must be receiving induction dosing with Skyrizi IV within 3 months of initiating therapy with Skyrizi subcutaneous. CONTINUATION THERAPY: ALL INDICATIONS: patient has responded to therapy.</p> |
| <b>Indications</b>         | All FDA-approved Indications.  |
| <b>Off Label Uses</b>      |  |
| <b>Part B Prerequisite</b> | No   |



# SOFOSBUVIR/VELPATASVIR

## Products Affected

- sofosbuvir-velpatasvir

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Combination use with other direct acting antivirals, excluding ribavirin.  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | 3 years or older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| <b>Coverage Duration</b>            | Criteria will be applied consistent with current AASLD/IDSA guidance.  |
| <b>Other Criteria</b>               | Criteria will be applied according to AASLD guidelines.  |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Indications consistent with current AASLD/IDSA guidance  |
| <b>Part B Prerequisite</b>          | No   |

# SOMAVERT

## Products Affected

- Somavert

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis, previous therapy, concomitant therapy   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an endocrinologist   |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# SORAFENIB

## Products Affected

- sorafenib

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Authorization will be for 1 year   |
| Other Criteria               | <p>Bone cancer, approve if the patient has recurrent chordoma or has osteosarcoma and has tried one standard chemotherapy regimen. GIST, approve if the patient has tried TWO of the following: imatinib mesylate, avapritinib, sunitinib, dasatinib, ripretinib or regorafenib. Differentiated (ie, papillary, follicular, oncocytic) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test and the medication is used in combination with azacitidine or decitabine or patient has had an allogeneic stem cell transplant and is in remission. Renal cell carcinoma (RCC)- approve if the patient has relapsed or advanced clear cell histology and the patient has tried at least one systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and sorafenib is used in combination with topotecan. HCC-approve if the patient has unresectable or metastatic disease. Soft tissue sarcoma-approve if the patient has angiosarcoma or desmoid tumors (aggressive fibromatosis) or solitary fibrous tumor/hemangiopericytoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. Please note for all diagnoses: Part B before Part D Step Therapy applies only to beneficiaries enrolled in a MA-PD plan</p> |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.   |

| PA Criteria                    | Criteria Details  |
|--------------------------------|---|
| <b>Off Label Uses</b>          | Bone cancer, Soft tissue sarcoma, gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, ovarian, fallopian tube, primary peritoneal cancer, myeloid/lymphoid neoplasms with eosinophilia |
| <b>Part B<br/>Prerequisite</b> | Yes   |

# SPRYCEL

## Products Affected

- dasatinib

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis for which dasatinib is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For melanoma, cutaneous- KIT mutation and previous therapies.  |
| <b>Age Restrictions</b>             | GIST/bone cancer/ melanoma, cutaneous-18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Authorization will be for 1 year  |
| <b>Other Criteria</b>               | For CML, patient must have Ph-positive or BCR::ABL1-positive CML. For ALL, patient must have Ph-positive ALL or ABL-class translocation. For Bone Cancer- approve if patient has chondrosarcoma or chordoma. GIST - approve if the patient has tried imatinib or avapritinib. For melanoma, cutaneous - approve if patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | GIST, bone cancer, melanoma cutaneous   |
| <b>Part B Prerequisite</b>          | No  |

# STELARA

## Products Affected

- Stelara subcutaneous

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD   |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous drugs tried.   |
| <b>Age Restrictions</b>             | PP-6 years and older (initial therapy).  |
| <b>Prescriber Restrictions</b>      | Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy).   |
| <b>Coverage Duration</b>            | Approve through end of plan year   |
| <b>Other Criteria</b>               | INITIAL THERAPY for USTEKINUMAB SC: PLAQUE PSORIASIS (PP) [A or B]: A) tried one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, psoralen plus PUVA) for at least 3 months, unless intolerant or B) contraindication to MTX. (Note: a 3-month trial or intolerance of at least one biologic that is not Stelara or a Stelara biosimilar also counts.) CROHN'S DISEASE (CD) [A and B]: A) receiving/received single IV loading dose within 2 months of initiating therapy with Ustekinumab SC, and B) (a, b, c or d): a) tried or is currently taking corticosteroids (CS), or CS are contraindicated, b) tried one conventional systemic therapy, c) has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, or d) had ileocolonic resection to reduce the chance of CD recurrence. ULCERATIVE COLITIS (UC) [A and B]: A) receiving/received single IV loading dose within 2 months of initiating therapy with Ustekinumab SC and B) meets one of the following (a or b): a) tried one systemic agent or b) has pouchitis and tried an antibiotic, probiotic, CS enema or mesalamine enema. CONTINUATION THERAPY: PP/PsA/CD/UC: patient has responded to therapy. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# STIVARGA

## Products Affected

- Stivarga

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | For GIST, (A or B): A) patient has previously been treated with (i and ii): i) imatinib or Ayvakit and ii) sunitinib or Sprycel, or B) medication is used as first-line therapy for succinate dehydrogenase (SDH)-deficient disease. For HCC, patient must have previously been treated with at least one systemic regimen. Soft tissue sarcoma, advanced or metastatic disease-approve if the patient has non-adipocytic sarcoma, angiosarcoma, or pleomorphic rhabdomyosarcoma. Bone Cancer-approve if the patient has relapsed/refractory or metastatic disease AND the patient has tried one systemic chemotherapy regimen AND pt has Ewing sarcoma or osteosarcoma. Colon and Rectal cancer/Appendiceal cancer-approve if the patient has advanced or metastatic disease, has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient meets one of the following (i or ii): i. patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type), the patient has tried an anti-EGFR therapy or the patient's tumor did not originate on the left side of the colon (from the splenic fixture to rectum) or ii. the patient's tumor or metastases has a RAS mutation (either KRAS mutation or NRAS mutation). CNS tumors (Glioblastoma or H3-mutated high-grade glioma)-approve if the patient has recurrent or progressive disease. Uterine sarcoma- (A and B): A) pt has recurrent, advanced, inoperable, or metastatic disease, and B) tried at least one systemic regimen. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |



| PA Criteria                | Criteria Details  |
|----------------------------|---|
| <b>Off Label Uses</b>      | Soft tissue Sarcoma, Bone Cancer, CNS tumors (Glioblastoma/H3-mutated high-grade glioma), Appendiceal cancer, Uterine sarcoma |
| <b>Part B Prerequisite</b> | No  |

# SUCRAID

## Products Affected

- Sucraid

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis, genetic and lab test results (as specified in the Other Criteria field)   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders   |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | Approve if the patient meets the following criteria (A and B): A) The diagnosis is established by one of the following (i or ii): i. Patient has endoscopic biopsy of the small bowel with disaccharidase levels consistent with congenital sucrose-isomaltase deficiency as evidenced by ALL of the following (a, b, c, and d): a) Decreased (usually absent) sucrase (normal reference: greater than 25 U/g protein), b) Decreased or normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein], c) Decreased maltase (normal reference: greater than 100 U/g protein), d) Decreased or normal lactase (normal reference: greater than 15 U/g protein) OR ii. Patient has a molecular genetic test demonstrating homozygous or compound heterozygous pathogenic or likely pathogenic sucrase-isomaltase gene variant AND B) Patient has symptomatic congenital sucrose-isomaltase deficiency (e.g., diarrhea, bloating, abdominal cramping). |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# SUNITINIB

## Products Affected

- sunitinib malate

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| 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) - approve if the patient has relapsed or advanced disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease. Pheochromocytoma/paraganglioma-approve if the patient has unresectable or metastatic disease. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| Off Label Uses               | Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and oncocytic carcinoma) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma, pheochromocytoma/paraganglioma, myeloid/lymphoid neoplasms with eosinophilia, GIST-unresectable succinate dehydrogenase (SDH)-deficient GIST, or use after avapritinib.  |

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# SYMDEKO

## Products Affected

- Symdeko

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

# TABRECTA

## Products Affected

- Tabrecta

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

# TADALAFIL

## Products Affected

- tadalafil oral tablet 2.5 mg, 5 mg

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

# TAFAMIDIS

## Products Affected

- Vyndaqel

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



# TAFINLAR

## Products Affected

- Tafinlar

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis for which Tafinlar is being used. BRAF V600 mutations |
| Age Restrictions             | 1 year and older  |
| Prescriber Restrictions      |   |
| Coverage Duration            | Authorization will be for 1 year                                |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>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 Tafenlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Mekinist. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c, or d): a) glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma OR d)Oligodendroglioma OR iii. Melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR patient has Erdheim Chester disease AND patient has BRAF V600-mutation positive disease. Metastatic or solid tumors-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets) AND patient has no satisfactory alternative treatment options. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer-approve if the patient meets the following (A, B, and C): A) Patient has recurrent disease, AND B) Patient has BRAF V600 mutation-positive disease, AND C) The medication will be taken in combination with Mekinist (trametinib tablets). Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Mekinist. Small bowel adenocarcinoma, approve if pt has BRAF V600E mutation-positive</p> |
|                       | <p>advanced or metastatic disease and this will be used with Mekinist AND (i or ii): i) this will be used as initial therapy and pt has received previous FOLFOX/CAPEOX therapy in the adjuvant setting within the past 12 months or has a contraindication, or (ii) this will be used as second-line and subsequent therapy.</p>  |
| <b>Indications</b>    | All FDA-approved Indications, Some Medically-accepted Indications.   |

| PA Criteria                | Criteria Details   |
|----------------------------|--|
| <b>Off Label Uses</b>      | Patients with Differentiated Thyroid Cancer, Biliary tract cancer, central nervous system cancer, histiocytic neoplasm, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, hairy cell leukemia, small bowel adenocarcinoma |
| <b>Part B Prerequisite</b> | No   |

# TAGRISO

## Products Affected

- Tagrisso

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | <p>NSCLC-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)-approve if the patient has advanced or metastatic disease, has EGFR mutation-positive NSCLC as detected by an approved test. Note-examples of EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has advanced or metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC-Post resection-approve if the patient has completely resected disease and has received previous adjuvant chemotherapy or if the patient is ineligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test. NSCLC- Unresectable Stage III - approve if the patient has locally advanced, unresectable (stage III) disease AND EGFR exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an approved test AND not had disease progression during or following platinum-based chemoradiation therapy. (Note: Patients could have received concurrent or sequential chemoradiation therapy.)</p> |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# TALVEY

## Products Affected

- Talvey

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

# TALZENNA

## Products Affected

- Talzenna

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis  |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| 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               |  |
| Part B Prerequisite          | No   |

# TASIGNA

## Products Affected

- Tasigna

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and melanoma, cutaneous, prior therapies tried. For melanoma, cutaneous, KIT mutation status.  |
| <b>Age Restrictions</b>             | GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older, ALL - 15 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.   |
| <b>Other Criteria</b>               | Acute lymphoblastic leukemia, philadelphia chromosome positive-approve. CML, philadelphia chromosome positive or BCR::ABL1-mutation positive chronic myeloid leukemia- approve. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafenib or ripretinib. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement. Pigmented villonodular synovitis/tenosynovial giant cell tumor-approve if the patient has tried Turalio or Romvimza or cannot take Turalio or Romvimza, according to the prescriber. For melanoma, cutaneous - approve if the patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>               | Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST), Pigmented villonodular synovitis/tenosynovial giant cell tumor, Myeloid/Lymphoid neoplasms with Eosinophilia, melanoma cutaneous.  |
| <b>Part B Prerequisite</b>          | No   |



# TAZAROTENE

## Products Affected

- tazarotene topical cream 0.1 %
- tazarotene topical gel

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

# TAZVERIK

## Products Affected

- Tazverik

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

# TEPMETKO

## Products Affected

- Tepmetko

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

# TERIPARATIDE

## Products Affected

- 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 |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/lifetime.  |
| Other Criteria               | INITIAL THERAPY: Postmenopausal Osteoporosis (PMO) Treatment, Increase Bone Mass in Men (see Note 1 below) with Primary or Hypogonadal Osteoporosis, and Treatment of Glucocorticosteroid-Induced Osteoporosis (GIO): (one of A, B, C, D or E): A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (PMO-ibandronate or zoledronic acid, all other diagnoses-zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past. CONTINUATION THERAPY: ALL INDICATIONS: if the patient has taken teriparatide for two years, approve if the patient is at high risk for fracture. Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density. Note 1: a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# TETRABENAZINE

## Products Affected

- tetrabenazine

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

# THALOMID

## Products Affected

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

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | MM, myelofibrosis, histiocytic neoplasms-18 years and older   |
| Prescriber Restrictions      |   |
| Coverage Duration            | Authorization will be for 1 year  |
| Other Criteria               | Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Myelofibrosis, approve if according to the prescriber the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/mL or if the patient has serum erythropoietin level less than 500 mU/mL and experienced no response or loss of response to erythropoietic stimulating agents. Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease. Castleman's disease-approve if the patient has multicentric Castleman's disease and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). Histiocytic neoplasms-approve if pt has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman cutaneous disease. |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.  |

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



# TIBSOVO

## Products Affected

- Tibsovo

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

# TOBRAMYCIN (NEBULIZATION)

## Products Affected

- tobramycin in 0.225 % NaCl

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

# TOLVAPTAN

## Products Affected

- tolvaptan

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent use with Jynarque.   |
| <b>Required Medical Information</b> | Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Authorization will be for 30 days for initial therapy, 3 months for continuation of therapy   |
| <b>Other Criteria</b>               | Hyponatremia, initial therapy (including new starts, patients on therapy for less than 30 days, and patients restarting therapy) - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on tolvaptan and has received less than 30 days of therapy.<br>Hyponatremia, continuation of therapy for patients established on therapy for at least 30 days - approve if the serum sodium level has increased from baseline (prior to initiating the requested drug) OR if the patient experienced improvement in at least one symptom, such as nausea, vomiting, headache, lethargy, or confusion. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# TOPICAL RETINOID PRODUCTS

## Products Affected

- tretinoin
- tretinoin microspheres topical gel
- tretinoin microspheres topical gel with pump  
0.04 %, 0.1 %

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

# TOPIRAMATE/ZONISAMIDE

## Products Affected

- Eprontia
- Zonisade

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Coverage is not provided for weight loss or smoking cessation. |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Authorization will be for 1 year.                              |
| Other Criteria               |  |
| Indications                  | All Medically-accepted Indications.                            |
| Off Label Uses               |  |
| 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   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Acute (i.e., non-chronic) pain.  |
| <b>Required Medical Information</b> | Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, sickle cell disease, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# TRANSMUCOSAL FENTANYL DRUGS

## Products Affected

- fentanyl citrate buccal lozenge on a handle

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| 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               |   |
| Part B Prerequisite          | No  |

# TREMFYA

## Products Affected

- Tremfya Pen
- Tremfya Pen Induction Pk-Crohn
- Tremfya subcutaneous

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)   |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | PP/UC/CD- 18 years of age and older (initial therapy)  |
| <b>Prescriber Restrictions</b>      | PP-Prescribed by or in consultation with a dermatologist (initial therapy only). PsA-prescribed by or in consultation with a dermatologist or rheumatologist (initial therapy). UC/CD-prescribed by or in consultation with a gastroenterologist (initial therapy).  |
| <b>Coverage Duration</b>            | Approve through end of plan year   |
| <b>Other Criteria</b>               | PP, initial therapy - approve if the pt meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: a biologic that is not a biosimilar of the requested product will also count) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. ULCERATIVE COLITIS- pt will receive 3 induction doses with Tremfya IV within 3 months of initiating Tremfya SC AND (A or B): A) tried a systemic therapy (e.g., 6-MP, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a CS) or B) has pouchitis and tried therapy with an antibiotic, probiotic, CS enema, or mesalamine (Rowasa) enema. CROHN'S DISEASE (CD) [one of A, B, C, or D]: A) tried or currently taking corticosteroid (CS) or CS is contraindicated, B) tried one other conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX], certolizumab, infliximab, ustekinumab, vedolizumab), C) had ileocolonic resection, or D) enterocutaneous (perianal or abdominal) or rectovaginal fistulas. PP/PsA/UC/CD continuation of therapy - approve if the pt is responding to therapy. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |



| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# TRIENTINE

## Products Affected

- trientine oral capsule 250 mg

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.   |
| <b>Coverage Duration</b>            | Authorization will be for 1 year   |
| <b>Other Criteria</b>               | For Wilson's Disease, approve if the patient meets A and B: A) Diagnosis of Wilson's disease is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, or d): a. Presence of Kayser-Fleischer rings, OR b. Serum ceruloplasmin levels less than 20mg/dL, OR c. Liver biopsy findings consistent with Wilson's disease, OR d. 24-hour urinary copper greater than 40 micrograms/24 hours, AND B) Patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant, OR 6) the patient has been started on therapy with trientine. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# TRIKAFTA

## Products Affected

- Trikafta

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko.  |
| <b>Required Medical Information</b> | Diagnosis, specific CFTR gene mutations, concurrent medications  |
| <b>Age Restrictions</b>             | 2 years of age and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF   |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | CF - Approve if the pt meets A, B and C: A) pt has at least one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# TRUQAP

## Products Affected

- Truqap

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | Breast Cancer-Approve if the patient meets the following (A, B, C, D and E): A) Patient has locally advanced or metastatic disease, AND B) Patient has hormone receptor positive (HR+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has at least one phosphatidylinositol 3-kinase (PIK3CA), serine/threonine protein kinase (AKT1), or phosphatase and tensin homolog (PTEN)-alteration, AND E) Patient meets one of the following (i or ii): i. Patient has had progression with at least one endocrine-based regimen in the metastatic setting (Note: Examples of endocrine therapy include anastrozole, exemestane, and letrozole.) and has had progression with at least one cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting (Note: Examples of CDK4/6 inhibitor include: Ibrance (palbociclib tablets or capsules), Verzenio (abemaciclib tablets), Kisqali (ribociclib tablets), Kisqali Femara Co-Pack (ribociclib and letrozole tablets) OR ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# TUKYSA

## Products Affected

- Tukysa

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis, prior therapies  |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Breast Cancer-approve if the patient has recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-amplified disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type). Biliary tract cancer-approve if the patient meets all of (a, b, c, and d): a) unresectable or metastatic disease, b) HER2 positive disease, c) tried at least one systemic regimen, d) will use in combination with trastuzumab. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Biliary tract cancer  |
| <b>Part B Prerequisite</b>          | No  |

# TURALIO

## Products Affected

- Turalio oral capsule 125 mg

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

# UCERIS

## Products Affected

- budesonide oral tablet, delayed and ext. release

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | The patient has experienced an inadequate treatment response, intolerance to a 4 week trial of an aminosalicylate (e.g. sulfasalazine, mesalamine) |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | 2 months   |
| Other Criteria               |  |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |
| Part B Prerequisite          | No   |

# VALCHLOR

## Products Affected

- Valchlor

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



# VALTOCO

## Products Affected

- Valtoco

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

# VANFLYTA

## Products Affected

- Vanflyta

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             | 18 years and older  |
| Prescriber Restrictions      |   |
| 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               |   |
| Part B Prerequisite          | No  |

# VENCLEXTA

## Products Affected

- Venclexta
- Venclexta Starting Pack

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis, prior therapy   |
| <b>Age Restrictions</b>             | 18 years and older (all diagnoses except ALL)  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | AML-approve if used in combination with azacitidine, decitabine, or cytarabine. CLL/SLL- approve. ALL- approve if relapsed/refractory disease and will be used in combination with chemotherapy. Hairy cell leukemia- approve if disease resistance to BRAF inhibitor therapy. Mantle Cell Lymphoma- approve if (A or B): A) the patient has tried at least one systemic regimen or B) patient has TP53 mutation and will use this as induction therapy in combination with Brukinsa (zanubrutinib) and Gazyva (obinutuzumab intravenous infusion). MDS- approve if pt meets (A and B): A) pt meets (i or ii): (i) has chronic myelomonocytic leukemia-2 or (ii) has higher risk disease (note: includes international prognostic scoring system (IPSS-R) intermediate-, high-, or very-high risk disease) and B) will use in combination with azacitidine or decitabine. Myeloproliferative neoplasm- approve if pt has accelerated or blast phase disease and will use in combination with azacitidine or decitabine. Multiple Myeloma- approve if the patient has t (11,14) translocation AND has tried at least one systemic regimen for multiple myeloma AND Venclexta will be used in combination with dexamethasone. Systemic light chain amyloidosis-approve if the patient has t (11, 14) translocation and has tried at least one systemic regimen. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |

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

# VERSACLOZ

## Products Affected

- Versacloz

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | For the treatment of a severely ill patient with schizophrenia who failed to respond adequately to standard antipsychotic treatment (i.e., treatment-resistant schizophrenia): 1) the patient has tried two oral antipsychotic agents (e.g., risperidone tablets/orally disintegrating tablets [ODT]/solution [Risperdal, generics], olanzapine tablets/ODT [Zyprexa/Zydis, generics], quetiapine tablets [Seroquel, generics], quetiapine extended-release tablets [Seroquel XR, generics], aripiprazole tablets [Abilify, generics], ziprasidone capsules [Geodon, generics], Fanapt tablets, Latuda tablets, Rexulti tablets, Vraylar capsules, asenapine sublingual tablets [Saprhis, generics], paliperidone ER tablets [Invega, generics]), Caplyta capsules OR 2) the patient is currently taking clozapine OR 3) the patient has taken clozapine at any time in the past |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

# VERZENIO

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## Products Affected

- Verzenio

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| 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      |   |
| Coverage Duration            | 1year   |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>Breast Cancer, Early-pt meets (A,B,C and D): A)Pt HR+disease, AND B) HER2-negative breast cancer, AND C)node-positive disease at high risk of recurrence AND D)meets 1 of the following (i or ii): i.Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one of the following (a,b, or c): a)Pt is postmenopausal woman, OR b)Pt is pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets 1 of the following (a or b): a)Pt is postmenopausal woman or man OR b)Pt is pre/perimenopausal woman and meets 1 of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Recurrent or Metastatic in Women-pt meets (A, B and C): A)has HR+ disease, AND B)Pt meets 1 of following criteria (i or ii): i.Pt is postmenopausal woman, OR ii.Pt is pre/perimenopausal woman and meets 1 of the following (a or b): a)receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt had surgical bilateral oophorectomy or ovarian irradiation, AND C) either (1 or 2): 1) HER2-negative breast cancer and Pt meets 1 of following criteria (i, ii, or iii): i.Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.pt meets following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)has tried chemo for metastatic breast cancer or 2)has HER2-positive breast cancer and has received at least 3 prior anti-HER2-based regimens in metastatic setting and will use this in combo with fulvestrant and trastuzumab.Breast Cancer-Recurrent or Metastatic in Men-pt meets following criteria (A and B): A)HR+ disease, AND B)either (1 or 2): 1) HER2-negative disease and Pt meets 1 of following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)receiving a GnRH analog, AND b)Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.Pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)Pt has tried chemo for metastatic breast cancer, or 2)</p> |
|                       | <p>has HER2-positive disease and has received at least 3 prior anti-HER2-based regimen in metastatic setting and will use this medication in combo with fulvestrant and trastuzumab. Endometrial cancer-pt meets all of (A, B, And C): A)has recurrent or metastatic disease, and B)has estrogen receptor (ER)-positive tumors, and C)will be using in combination with letrozole.</p>  |
| <b>Indications</b>    | All FDA-approved Indications, Some Medically-accepted Indications.  |

|                                |                         |
|--------------------------------|-------------------------|
| <b>PA Criteria</b>             | <b>Criteria Details</b> |
| <b>Off Label Uses</b>          | Endometrial cancer      |
| <b>Part B<br/>Prerequisite</b> | No                      |



# VIGABATRIN

## Products Affected

- vigabatrin
- Vigadrone
- Vigpoder

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

# VITRAKVI

## Products Affected

- Vitrakvi

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis, NTRK gene fusion status  |
| <b>Age Restrictions</b>             | Pediatric Diffuse High-Grade Glioma- less than or equal to 21 years old   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Solid tumors - approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity. Pediatric diffuse high grade glioma - approve if (A and B): A) tumor is positive for NTRK gene fusion and B) meets (i or ii): i) medication is used as adjuvant therapy or ii) medication is used for recurrent or progressive disease. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Pediatric Diffuse High-Grade Glioma   |
| <b>Part B Prerequisite</b>          | No  |

# VIZIMPRO

## Products Affected

- Vizimpro

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis, EGFR status, exon deletions or substitutions  |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| 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.<br>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               |  |
| Part B Prerequisite          | No   |

# VONJO

## Products Affected

- Vonjo

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis  |
| Age Restrictions             | 18 years and older   |
| Prescriber Restrictions      |  |
| 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 10 <sup>9</sup> /L (less than 50,000/mcL) OR (B) Patient has a platelet count of greater than or equal to 50 x 10 <sup>9</sup> /L (greater than or equal to 50,000/mcL) and has high-risk disease, OR (C) patient has myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease-related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis). |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.   |
| Off Label Uses               | Accelerated or blast phase myeloproliferative neoplasm   |
| Part B Prerequisite          | No   |

# VORANIGO

## Products Affected

- Voranigo

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Diagnosis   |
| Age Restrictions             | 12 years and older  |
| Prescriber Restrictions      |   |
| Coverage Duration            | 1 year  |
| Other Criteria               | GLIOMAS-All of (A, B and C): A. Susceptible isocitrate dehydrogenase-1 (IDH1) or IDH2 mutation-positive disease, AND B. Grade 2 oligodendroglioma OR Grade 2 astrocytoma, AND C. Prior surgery, including biopsy, sub-total resection, or gross total resection |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |
| Part B Prerequisite          | No  |

# VORICONAZOLE (ORAL)

## Products Affected

- voriconazole

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Aspergillus-Prophy, systemic w/risk neutropenia-Prophy, systemic w/HIV-Prophy/Tx-6 mo, others-3 mo  |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Aspergillus Infections - prophylaxis, oropharyngeal candidiasis (fluconazole-refractory) - treatment, candida 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. |
| <b>Part B Prerequisite</b>          | No  |

# VOTRIENT

## Products Affected

- pazopanib

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | 18 years and older  |
| Prescriber Restrictions      |   |
| 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, oncocytic) 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. |
| Indications                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| Off Label Uses               | Differentiated (ie, papillary, follicular, oncocytic) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma, bone cancer.  |

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |



# VOWST

## Products Affected

- Vowst

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

# WELIREG

## Products Affected

- Welireg

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Renal Cell Carcinoma- approve if pt has advanced disease AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND has tried at least one a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). [Note: Examples of PD-1 inhibitor or PD-L1 inhibitor include: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Bavencio (avelumab intravenous infusion). Examples of VEGF-TKI include Cabometyx (cabozantinib tablets), Lenvima (lenvatinib capsules), Inlyta (axitinib tablets), Fotivda (tivozanib capsules), pazopanib, sunitinib, and sorafenib.] Van Hippel-Lindau Disease-approve if the patient meets the following (A, B, and C): A) Patient has a von Hippel-Lindau (VHL) germline alteration as detected by genetic testing, B) Does not require immediate surgery and C) Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv): i. Central nervous system hemangioblastomas, OR ii. Pancreatic neuroendocrine tumors, OR iii. Renal cell carcinoma, OR iv. Retinal hemangioblastoma. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# XALKORI

## Products Affected

- Xalkori

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

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# XDEMIVY

## Products Affected

- Xdemivy

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

# XERMELO

## Products Affected

- Xermelo

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis, previous therapy, concomitant therapy   |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| 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               |  |
| Part B Prerequisite          | No   |

# XIFAXAN

## Products Affected

- Xifaxan oral tablet 550 mg

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis   |
| <b>Age Restrictions</b>             | Hepatic encephalopathy, irritable bowel syndrome with diarrhea - 18 years of age or older.  |
| <b>Prescriber Restrictions</b>      | Pouchitis - prescribed by or in consultation with a gastroenterologist  |
| <b>Coverage Duration</b>            | Hep Enceph-6mo, IBS/diarrhea-14days, Sm intest bacterial overgrowth-14days, Pouchitis - 1 year  |
| <b>Other Criteria</b>               | Hepatic Encephalopathy-approve if the patient has previously had overt hepatic encephalopathy and the requested medication will be used concomitantly with lactulose, unless the patient has a contraindication or significant intolerance to treatment with lactulose. Irritable bowel syndrome with diarrhea-approve. Small intestine bacterial overgrowth-approve if the diagnosis has been confirmed by a glucose hydrogen breath test, lactulose hydrogen breath test, or small bowel aspiration and culture. Chronic antibiotic-dependent pouchitis- approve Xifaxan if patient meets all of (a, b, c and d): a) recurrent pouchitis (Note: recurrent pouchitis is typically considered history of at least 3 pouchitis episodes within a 12 month period), and b) episodes of pouchitis respond to antibiotic therapy but relapse shortly after antibiotic discontinuation, and c) alternative causes of recurrent pouchitis have been ruled out, and d) has tried long-term antibiotic therapy trials (at least 4 weeks) of BOTH ciprofloxacin and metronidazole for remission maintenance. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Small intestine bacterial overgrowth, chronic antibiotic-dependent pouchitis  |
| <b>Part B Prerequisite</b>          | No  |

# XOLAIR

## Products Affected

- Xolair

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | Concurrent use with another monoclonal antibody therapy.  |
| Required Medical Information | Diagnosis   |
| 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  |



| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>MODERATE TO SEVERE PERSISTENT ASTHMA (A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, and B) baseline positive skin test or in vitro test for 1 or more perennial or seasonal aeroallergens C) received at least 3 months of combination therapy with an inhaled corticosteroid (ICS) and additional asthma controller/maintenance medication (e.g., LABA, LAMA, leukotriene receptor antagonist, monoclonal antibody) [see Exception 1 below] and D) asthma is uncontrolled or was uncontrolled prior to receiving Xolair or another monoclonal antibody and meets one of the following (a, b, c, d, or e): a) experienced two or more asthma exacerbations requiring systemic CSs in the past year, b) experienced one or more asthma exacerbation requiring hospitalization/urgent care visit/emergency department visit in the past year, c) forced expiratory volume in 1 second (FEV1) less than 80% predicted, d) FEV1/forced vital capacity (FVC) less than 0.80, or e) asthma worsens upon tapering of oral CS. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRwNP) [all of A, B, C, D, and E]: A) diagnosis by direct exam, endoscopy, or sinus CT scan, B) baseline (prior to Xolair or another monoclonal antibody that may lower IgE) IgE at least 30 IU/ml, C) at least two of the following symptoms for 6 months: nasal congestion, obstruction, discharge, reduction/loss of smell, D) tried intranasal CS and will continue in combination with Xolair, and E) one of the following (a, b, or c): a) had systemic CS at least 5 days in past 2 years, b) contraindication to systemic CS, or c) had nasal polyp surgery. CHRONIC IDIOPATHIC URTICARIA (CIU): urticaria more than 6 weeks prior to treatment with Xolair with symptoms present more than 3 days per week despite daily non-sedating H1-antihistamine therapy. IgE-MEDIATED FOOD ALLERGY (all of A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, B) positive skin prick test or positive in vitro test for IgE to one or more foods, C) history of allergic reaction that met all of the following (a, b, and c): a) signs and symptoms of a significant systemic allergic reaction, b) reaction occurred within a short period of time following a known ingestion of the food, and c) prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector, and D) patient has been prescribed an epinephrine auto-injector. CONTINUATION THERAPY: ASTHMA: patient responded to therapy and continues to receive an ICS. CRwNP: patient responded after 6 months of therapy and continues intranasal CS. CIU: patient responded to therapy. Exception 1: an</p> |
|                       | <p>exception to the requirement of a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS.</p>  |
| <b>Indications</b>    | All FDA-approved Indications.  |
| <b>Off Label Uses</b> |  |

| PA Criteria                    | Criteria Details |
|--------------------------------|------------------|
| <b>Part B<br/>Prerequisite</b> | No               |

# XOSPATA

## Products Affected

- Xospata

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

# XPOVIO

## Products Affected

- Xpovio

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Diagnosis, prior therapies   |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | <p>Multiple Myeloma-Approve if the patient meets the following (A and B): A) The medication will be taken in combination with dexamethasone AND B) Patient meets one of the following (i, ii, or iii): i. Patient has tried at least four prior regimens for multiple myeloma OR ii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib OR iii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with Darzalex (daratumumab infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Kyprolis (carfilzomib infusion)/Revlimid/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma (Note: this includes patients with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma) -approve if the patient has been treated with at least two prior systemic therapies.</p> |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.   |

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

# XTANDI

## Products Affected

- Xtandi

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Diagnosis for which Xtandi is being used.   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Authorization will be for 1 year  |
| <b>Other Criteria</b>               | Prostate cancer-castration-resistant [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy. Prostate cancer- Non-Metastatic, Castration-Sensitive - approve if pt has biochemical recurrence and is at high risk for metastasis. [Note: High-risk biochemical recurrence is defined as prostate-specific antigen (PSA) doubling time less than or equal to 9 months.] |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |

# XYREM

## Products Affected

- sodium oxybate

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

# ZEJULA

## Products Affected

- Zejula oral tablet

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after platinum-based chemotherapy regimen and if the patient is new to therapy they must have a trial of Lynparza prior to approval of Zejula. Patients who have had a complete or partial response to first-line platinum based chemotherapy and do not have BRCA altered disease are not required to try Lynparza. Uterine leiomyosarcoma- approve if the patient has BRCA2-altered disease and has tried one systemic regimen. In addition, patients new to therapy must have a trial of Lynparza prior to approval of Zejula. Ovarian, fallopian tube or primary peritoneal cancer in the treatment setting-approve. |
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically-accepted Indications.  |
| <b>Off Label Uses</b>               | Uterine Leiomyosarcoma, Ovarian, fallopian tube or primary peritoneal cancer-treatment  |
| <b>Part B Prerequisite</b>          | No  |



# ZELBORAF

## Products Affected

- Zelboraf

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

| PA Criteria                | Criteria Details   |
|----------------------------|--|
| <b>Off Label Uses</b>      | Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or oncocytic carcinoma) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm |
| <b>Part B Prerequisite</b> | No   |

# ZOLINZA

## Products Affected

- Zolinza

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

# ZTALMY

## Products Affected

- Ztalmy

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

# ZURZUVAE

## Products Affected

- Zurzuvae

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

# ZYDELIG

## Products Affected

- Zydelig

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

# ZYKADIA

## Products Affected

- Zykadia

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

# ZYPREXA RELPREVV

## Products Affected

- Zyprexa Relprevv

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Tolerability with oral olanzapine has been established. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.                           |
| <b>Off Label Uses</b>               |   |
| <b>Part B Prerequisite</b>          | No  |



# ZYTIGA

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## Products Affected

- abiraterone
- Abirtega

| PA Criteria                  | Criteria Details                 |
|------------------------------|----------------------------------|
| Exclusion Criteria           |                                  |
| Required Medical Information |                                  |
| Age Restrictions             | 18 years and older               |
| Prescriber Restrictions      |                                  |
| Coverage Duration            | Authorization will be for 1 year |

| PA Criteria                | Criteria Details   |
|----------------------------|--|
| <b>Other Criteria</b>      | <p>Prostate Cancer-Metastatic, Castration-Resistant (mCRPC)-Approve if abiraterone is being used in combination with prednisone or dexamethasone and the medication is used concurrently used with a gonadotropin-releasing hormone (GnRH) analog (see Note 1) or the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration-sensitive (mCSPC)-approve if the medication is used in combination with prednisone and the medication is concurrently used with a GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the patient meets all of the following criteria (A, B, and C): A) abiraterone is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii): i. abiraterone with prednisone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer-very-high-risk-group-approve if according to the prescriber the patient is in the very-high-risk group, the medication will be used in combination with prednisone, the medication will be used in combination with external beam radiation therapy and the patient meets one of the following criteria (i or ii): i. abiraterone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer- radical prostatectomy or post radiation therapy-approve if patient meets (A, B, C and D): A) the medication is used in combination with prednisone, B) meets (i or ii): i) the patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy or ii) PSA recurrence or positive digital rectal examination (DRE) after radiation therapy, C) patient has pelvic recurrence or positive regional lymph nodes, and D) the medication will be used concurrently with GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Salivary Gland Tumors- approve if (A, B and C): A) used in combination with prednisone, B) androgen receptor-positive (AR+) recurrent, unresectable or metastatic tumor, and C) used in combination with a GnRH analog (see Note 1). Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).</p> |
| <b>Indications</b>         | All FDA-approved Indications, Some Medically-accepted Indications.   |
| <b>Off Label Uses</b>      | Prostate Cancer-Regional Risk Group, Prostate cancer-very-high-risk group, Prostate cancer- radical prostatectomy or post radiation, Salivary Gland Tumors   |
| <b>Part B Prerequisite</b> | No   |