# ABILIFY ASIMTUFII

## Products Affected

- Abilify Asimtufii

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Tolerability with oral aripiprazole has been established. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ABILIFY MYCITE

## Products Affected

- Abilify Mycite Maintenance Kit
- Abilify Mycite Starter Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. For acute treatment of manic or mixed episodes associated with bipolar I disorder: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to brand Vraylar. For maintenance treatment of bipolar I disorder: The patient experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine, risperidone, ziprasidone. For adjunctive treatment of major depressive disorder (MDD): 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, olanzapine, quetiapine, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Rexulti, Vraylar. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | N/A |

# ABIRATERONE

## Products Affected

- Abiraterone Acetate
- Zytiga

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Node-positive (N1), non-metastatic (M0) prostate cancer and very-high-risk prostate cancer. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ACITRETIN

## Products Affected

- Acitretin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Prevention of non-melanoma skin cancers in high risk individuals, Lichen planus, Keratosis follicularis (Darier Disease) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Psoriasis: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate or cyclosporine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ACTEMRA

## Products Affected

- Actemra
- Actemra Actpen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Castleman's disease |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active systemic juvenile idiopathic arthritis (JIA) (new starts only): 1) patient has experienced an inadequate treatment response to a nonsteroidal anti-inflammatory drug (NSAID) trial, a corticosteroid, methotrexate, or leflunomide, OR 2) inadequate treatment response or intolerance to a prior biologic DMARD. For moderately to severely active polyarticular juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ACTHAR HP

## Products Affected

- Acthar
- Acthar Gel

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the following diagnoses, patient has experienced an inadequate treatment response to a parenteral or an oral glucocorticoid (for ophthalmic diseases only, inadequate response to a trial of a topical ophthalmic glucocorticoid is also acceptable): 1) For rheumatic disorders (e.g., psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis): The requested drug must be used as adjunctive treatment, 2) For nephrotic syndrome: the requested drug must be requested for induction of diuresis or for remission of proteinuria, 3) For multiple sclerosis (MS): patient has an acute exacerbation of MS, 4) Collagen diseases (e.g., systemic lupus erythematosus, dermatomyositis, or polymyositis), 5) Dermatologic diseases (e.g., severe erythema multiforme, Stevens-Johnson syndrome), 6) Ophthalmic diseases, acute or chronic (e.g., iritis, keratitis, optic neuritis), 7) Symptomatic sarcoidosis, 8) Serum sickness. For infantile spasms (IS): for continuation of therapy, patient must show substantial clinical benefit from therapy. |
| **Age Restrictions** | For infantile spasms (IS) initial request: patient is less than 2 years of age |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | IS: 6 months. MS exacerbation: 3 wks. Serum sickness: 1 month. All other diagnoses: 3 months |
| **Other Criteria** | N/A |

# ACTIMMUNE

## Products Affected

- Actimmune INJ 100MCG/0.5ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Mycosis fungoides, Sezary syndrome. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ADAKVEO

## Products Affected

- Adakveo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 16 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# ADALIMUMAB AET

## Products Affected

- Abrilada
- Abrilada 1-pen Kit
- Adalimumab-aaty 1-pen Kit
- Adalimumab-aaty 2-pen Kit
- Adalimumab-aaty 2-syringe Kit
- Adalimumab-adaz
- Adalimumab-adbm
- Adalimumab-adbm Crohns/uc/hs Starter
- Adalimumab-adbm Psoriasis/uveitis Starter
- Adalimumab-adbm Starter Package For Crohns Disease/uc/hs
- Adalimumab-adbm Starter Package For Psoriasis/uveitis
- Adalimumab-fkjp
- Adalimumab-ryvk
- Adalimumab-ryvk (2 Pen)
- Amjevita
- Cyltezo
- Cyltezo Starter Package For Crohns Disease/uc/hs
- Cyltezo Starter Package For Psoriasis
- Cyltezo Starter Package For Psoriasis/uveitis
- Hadlima
- Hadlima Pushtouch
- Hulio
- Hyrimoz
- Hyrimoz Crohn's Disease And Ulcerative Colitis Starter Pack
- Hyrimoz Pediatric Crohns Disease Starter Pack
- Hyrimoz Pediatric Crohn'sdisease Starter Pack
- Hyrimoz Plaque Psoriasis/uveitis Starter Pack
- Simlandi 1-pen Kit
- Simlandi 2-pen Kit
- Yuflyma 1-pen Kit
- Yuflyma 2-syringe Kit
- Yuflyma Cd/uc/hs Starter
- Yusimry

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-radiographic axial spondyloarthritis, Behcet's syndrome |
| **Exclusion Criteria** | N/A |

| | |
|---|---|
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active ankylosing spondylitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Taltz (ixekizumab). For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | For an adult with moderately to severely active Crohn's disease (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab). For active psoriatic arthritis (PsA) (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For moderately to severely active polyarticular juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For moderate to severe hidradenitis suppurativa, Behcet's, and non-infectious intermediate, posterior or panuveitis: (new starts only): patient has experienced an intolerable adverse event and that adverse event was NOT attributed to the active ingredient as described in the prescribing information to one of the following: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf). For moderately to severely active ulcerative colitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). |

# ADAPALENE

## Products Affected

- Adapalene CREA
- Adapalene GEL
- Adapalene PADS
- Adapalene SOLN
- Adapalene Pump
- Adapalene/benzoyl Peroxide
- Cabtreo
- Differin CREA
- Differin GEL 0.3%
- Differin LOTN
- Epiduo
- Epiduo Forte

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ADBRY

## Products Affected

- Adbry

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For atopic dermatitis, initial therapy: 1) patient has moderate-to-severe disease, AND 2) patient has had an inadequate treatment response to either a topical corticosteroid or a topical calcineurin inhibitor OR topical corticosteroids and topical calcineurin inhibitors are not advisable for the patient. For atopic dermatitis, continuation of therapy: the patient achieved or maintained positive clinical response. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 4 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# ADEMPAS

## Products Affected

- Adempas

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. For chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4): 1) Patient has persistent or recurrent CTEPH after pulmonary endarterectomy (PEA), OR 2) Patient has inoperable CTEPH with the diagnosis confirmed by right heart catheterization AND by computed tomography (CT), magnetic resonance imaging (MRI), or pulmonary angiography. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ADLARITY

## Products Affected

- Adlarity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Vascular dementia |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient is unable to take oral dosage forms (e.g., difficulty swallowing tablets or capsules). For dementia of the Alzheimer's type: the patient has experienced an inadequate response, intolerance, or the patient has a contraindication to rivastigmine transdermal patch. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ADZYNMA

## Products Affected

- Adzynma

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For congenital thrombotic thrombocytopenic purpura (cTTP), initial: Diagnosis has been confirmed by genetic testing or enzyme assay with biallelic mutations in the ADAMTS13 gene. For cTTP, continuation: Patient is responding to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# AGAMREE

## Products Affected

- Agamree

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of Duchenne muscular dystrophy (DMD): 1) The diagnosis was confirmed by genetic testing identifying a disease-causing mutation of the DMD gene AND 2) The patient has tried prednisone and experienced any of the following a) unmanageable and/or clinically significant weight gain/obesity, b) unmanageable and/or clinically significant psychiatric/behavioral issues such as abnormal behavior, aggression, or irritability, or c) clinically significant growth stunting. |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AIMOVIG

## Products Affected

- Aimovig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug, and the patient had a reduction in migraine days per month from baseline. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 3 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# AJOVY

**Products Affected**

- Ajovy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants. For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug, and the patient had a reduction in migraine days per month from baseline. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 3 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# AKEEGA

## Products Affected

- Akeega

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AKLIEF

**Products Affected**

- Aklief

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 9 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ALDURAZYME

## Products Affected

- Aldurazyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For mucopolysaccharidosis I (MPS I): Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of alpha-L-iduronidase enzyme activity and/or by genetic testing. Patients with Scheie form (i.e., attenuated MPS I) must have moderate to severe symptoms. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ALECENSA

**Products Affected**

- Alecensa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent ALK-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC, ALK-positive anaplastic large-cell lymphoma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic OR 2) the requested drug will be used as adjuvant treatment following tumor resection. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ALIQOPA

**Products Affected**

- Aliqopa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Extranodal marginal zone lymphoma (EMZL) of the stomach, EMZL of nongastric sites (noncutaneous), nodal marginal zone lymphoma, splenic marginal zone lymphoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For follicular lymphoma, extranodal marginal zone lymphoma (EMZL) of the stomach, EMZL of nongastric sites (noncutaneous), nodal marginal zone lymphoma, and splenic marginal zone lymphoma: 1) the disease is relapsed or refractory AND 2) the requested drug will be used as subsequent therapy after at least 2 prior therapies. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ALKINDI

## Products Affected

- Alkindi Sprinkle

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For adrenocortical insufficiency: 1) Patient requires a strength that is not available in hydrocortisone tablets (e.g., 0.5 mg, 1 mg, or 2 mg) OR 2) Patient has difficulty swallowing hydrocortisone tablets. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ALOSETRON

## Products Affected

- Alosetron Hydrochloride
- Lotronex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For severe diarrhea-predominant irritable bowel syndrome (IBS): 1) The requested drug is being prescribed for a biological female or a person that self-identifies as a female, 2) chronic IBS symptoms lasting at least 6 months, 3) gastrointestinal tract abnormalities have been ruled out, AND 4) inadequate response to one conventional therapy (e.g., antispasmodics, antidepressants, antidiarrheals). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ALPHA1-PROTEINASE INHIBITOR

## Products Affected

- Aralast Np INJ 1000MG, 500MG
- Glassia
- Prolastin-c
- Zemaira

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For alpha1-proteinase inhibitor deficiency: Patient must have 1) clinically evident emphysema, AND 2) pretreatment serum alpha1-proteinase inhibitor level less than 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ALUNBRIG

**Products Affected**

- Alunbrig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC, inflammatory myofibroblastic tumors (IMT) with ALK translocation. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic AND 2) the disease is anaplastic lymphoma kinase (ALK)-positive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ALVAIZ

**Products Affected**

- Alvaiz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic or persistent immune thrombocytopenia (ITP) (new starts): 1) Patient (pt) has experienced an inadequate treatment response or is intolerant to a prior therapy such as corticosteroids or immunoglobulins, AND 2) Untransfused platelet (plt) count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000-50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes pt to trauma). For ITP (continuation): plt count response to the requested drug: 1) Current plt count is less than or equal to 200,000/mcL, OR 2) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to a plt count sufficient to avoid clinically important bleeding. For thrombocytopenia associated with chronic hepatitis C (new starts): the requested drug is used for initiation and maintenance of interferon-based therapy. For thrombocytopenia associated with chronic hepatitis C (continuation): pt is receiving interferon-based therapy. For severe aplastic anemia (AA) (new starts): Pt had an insufficient response to immunosuppressive therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | HCV: 6mo, ITP/AA initial: 6mo, ITP reauth: Plan Year, AA reauth: APR-Plan Year, IPR-16 wks |

| | |
|---|---|
| **Other Criteria** | For severe AA (continuation): 1) Current plt count is 50,000-200,000/mcL, OR 2) Current plt count is less than 50,000/mcL and pt has not received appropriately titrated therapy for at least 16 weeks, OR 3) Current plt count is less than 50,000/mcL and pt is transfusion-independent, OR 4) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to achieve and maintain an appropriate target plt count. APR: adequate platelet response (greater than 50,000/mcL), IPR: inadequate platelet response (less than 50,000/mcL). |

# ALYMSYS

**Products Affected**

- Alymsys

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Ampullary adenocarcinoma, breast cancer, central nervous system (CNS) cancers, malignant pleural mesothelioma, malignant peritoneal mesothelioma, pericardial mesothelioma, tunica vaginalis testis mesothelioma, soft tissue sarcomas, uterine neoplasms, endometrial carcinoma, vulvar cancers, small bowel adenocarcinoma, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications except ophthalmic-related disorders: The patient had an intolerable adverse event to Zirabev and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# AMBRISENTAN

## Products Affected

- Ambrisentan
- Letairis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AMITIZA AET

## Products Affected

- Amitiza
- Lubiprostone

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C): The patient experienced an inadequate treatment response, intolerance, or has a contraindication that would prohibit a trial of Linzess (linaclotide). Opioid-Induced Constipation (OIC): The patient experienced an inadequate treatment response, intolerance, or has a contraindication that would prohibit a trial of Movantik (naloxegol). |
| **Age Restrictions** | Irritable Bowel Syndrome with Constipation (IBS-C): 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AMONDYS 45

## Products Affected

- Amondys 45

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AMVUTTRA

## Products Affected

- Amvuttra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For polyneuropathy of hereditary transthyretin-mediated amyloidosis, initial therapy: patient is positive for a mutation of the TTR gene and exhibits clinical manifestation of disease. For polyneuropathy of hereditary transthyretin-mediated amyloidosis, continuation of therapy: patient demonstrates a beneficial response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# APOKYN

## Products Affected

- Apokyn INJ 30MG/3ML
- Apomorphine Hydrochloride INJ

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of "off" episodes in Parkinson's disease, continuation: The patient is experiencing improvement on the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ARANESP AET

**Products Affected**

- Aranesp Albumin Free INJ 100MCG/0.5ML, 100MCG/ML, 10MCG/0.4ML, 150MCG/0.3ML, 200MCG/0.4ML, 200MCG/ML, 25MCG/0.42ML, 25MCG/ML, 300MCG/0.6ML, 40MCG/0.4ML, 40MCG/ML, 500MCG/ML, 60MCG/0.3ML, 60MCG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Anemia in patients with myelodysplastic syndrome (MDS). |
| **Exclusion Criteria** | Patients receiving chemotherapy with curative intent. Patients with myeloid cancer. |
| **Required Medical Information** | For all uses: Patient has experienced an inadequate response to or has an intolerance or a contraindication to Procrit (erythropoietin injection). Requirements regarding hemoglobin (Hgb) values exclude values due to a recent transfusion. For initial approval: 1) for anemia due to chronic kidney disease (CKD): patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%), AND 2) for all uses: pretreatment (no erythropoietin treatment in previous month) hemoglobin (Hgb) is less than 10 g/dL, AND 3) for anemia in patients with myelodysplastic syndrome (MDS): pretreatment serum erythropoietin (EPO) level is 500 international units/L or less. For reauthorizations (patient received erythropoietin treatment in previous month) in all uses: 1) Patient has received at least 12 weeks of erythropoietin therapy, AND 2) Patient responded to erythropoietin therapy, AND 3) Current Hgb is less than 12 g/dL, AND 4) for CKD: patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 16 weeks |

| | |
|---|---|
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual (e.g., used for treatment of anemia for a patient with chronic renal failure who is undergoing dialysis, or furnished from physician's supply incident to a physician service). |

# ARCALYST

## Products Affected

- Arcalyst

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Prevention of gout flares in patients initiating or continuing urate-lowering therapy. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (new starts): 1) two or more gout flares within the previous 12 months, AND 2) inadequate response, intolerance, or contraindication to maximum tolerated doses of a non-steroidal anti-inflammatory drug (NSAID) and colchicine, AND 3) concurrent use with urate-lowering therapy. For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (continuation): 1) patient must have achieved or maintained a clinical benefit (i.e., a fewer number of gout attacks or fewer flare days) compared to baseline, AND 2) continued use of urate-lowering therapy concurrently with the requested drug. For recurrent pericarditis: patient must have had an inadequate response, intolerance, or contraindication to maximum tolerated doses of an NSAID and colchicine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ARESTIN AET

## Products Affected

- Arestin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate response, intolerance, or has a contraindication to treatment with systemic, oral, low-dose doxycycline (i.e., doxycycline 20 mg). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ARIKAYCE

## Products Affected

- Arikayce

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ARMODAFINIL

## Products Affected

- Armodafinil
- Nuvigil

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For excessive sleepiness associated with narcolepsy: The diagnosis has been confirmed by sleep lab evaluation. For excessive sleepiness associated with obstructive sleep apnea (OSA): The diagnosis has been confirmed by polysomnography. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ARZERRA

## Products Affected

- Arzerra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Waldenstrom macroglobulinemia (WM), lymphoplasmacytic lymphoma (LPL) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For WM and LPL: the patient has experienced an intolerance to rituximab. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ASPARLAS

## Products Affected

- Asparlas

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 21 years of age or younger |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ASPRUZYO

**Products Affected**

- Aspruzyo Sprinkle

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic angina: 1) The patient has tried ranolazine tablets OR 2) The patient is unable to take ranolazine tablets for any reason (e.g., difficulty swallowing tablets, requires nasogastric administration). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AUBAGIO

## Products Affected

- Aubagio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AUGTYRO

## Products Affected

- Augtyro CAPS 40MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AURYXIA

## Products Affected

- Auryxia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug is not being prescribed for treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AUSTEDO

## Products Affected

- Austedo
- Austedo Xr
- Austedo Xr Patient Titration Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Tourette's syndrome |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AUVELITY

**Products Affected**

- Auvelity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Major Depressive Disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AVASTIN

**Products Affected**

- Avastin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Ampullary adenocarcinoma, breast cancer, central nervous system (CNS) cancers, malignant pleural mesothelioma, malignant peritoneal mesothelioma, pericardial mesothelioma, tunica vaginalis testis mesothelioma, soft tissue sarcomas, uterine neoplasms, endometrial carcinoma, vulvar cancers, small bowel adenocarcinoma, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications except ophthalmic-related disorders: The patient had an intolerable adverse event to Zirabev and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# AVONEX AET

## Products Affected

- Avonex INJ 30MCG/0.5ML
- Avonex Pen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# AVSOLA

## Products Affected

- Avsola

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Behcet's syndrome, hidradenitis suppurativa, juvenile idiopathic arthritis, pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, uveitis. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) Pt meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) or leflunomide OR b) intolerance or CI to MTX AND leflunomide, AND 2) Pt meets ANY of the following: a) inadequate response, intolerance or CI to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at time of diagnosis, AND 2) Pt meets ANY of the following: a) pt has experienced inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with MTX, cyclosporine, or acitretin, OR b) pharmacologic treatment with MTX, cyclosporine, or acitretin is contraindicated, OR c) pt has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | For hidradenitis suppurativa (new starts only): Pt has severe, refractory disease. For uveitis (new starts only): Inadequate response or intolerance or has a CI to a trial of immunosuppressive therapy for uveitis. For FDA-approved indications and off-label uses that overlap: The patient had an intolerable adverse event to Renflexis and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. |

# AVYCAZ

## Products Affected

- Avycaz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# AYVAKIT

**Products Affected**

- Ayvakit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Myeloid and lymphoid neoplasms with eosinophilia, gastrointestinal stromal tumor (GIST) for unresectable, recurrent, or metastatic disease without platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For myeloid and lymphoid neoplasms with eosinophilia, the patient meets all of the following criteria: 1) The disease is FIP1L1- PDGFRA rearrangement-positive, AND 2) The disease harbors a PDGFRA D842A mutation, AND 3) The disease is resistant to imatinib. For GIST, the patient meets either of the following criteria: 1) The disease harbors PDGFRA exon 18 mutation, including PDGFRA D842V mutations, OR 2) The requested drug will be used after failure on at least two Food and Drug Administration (FDA)-approved therapies in unresectable, recurrent, or metastatic disease without PDGFRA exon 18 mutation. For systemic mastocytosis: 1) The patient has a diagnosis of indolent systemic mastocytosis or advanced systemic mastocytosis (including aggressive systemic mastocytosis [ASM], systemic mastocytosis with associated hematological neoplasm [SM-AHN], and mast cell leukemia [MCL]) AND 2) The patient has a platelet count of greater than or equal to 50,000/microliter (mcL). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BAFIERTAM AET

## Products Affected

- Bafiertam

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease]: Patient must have tried and failed or has a contraindication or intolerance to two of the following: brand Aubagio, Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone, brand Tecfidera, Vumerity (diroximel fumarate), Zeposia (ozanimod). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BALVERSA

## Products Affected

- Balversa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For urothelial carcinoma: 1) disease has susceptible fibroblast growth factor receptor 3 (FGFR3) or fibroblast growth factor receptor 2 (FGFR2) genetic alterations AND 2) the requested drug will be used as subsequent therapy for any of the following: a) locally advanced or metastatic urothelial carcinoma, b) recurrent primary carcinoma of the urethra, c) stage II-IV urothelial carcinoma of the bladder, d) urothelial carcinoma of the bladder with metastatic or local recurrence post cystectomy, or e) urothelial carcinoma of the bladder with muscle invasive local recurrence or persistent disease in a preserved bladder. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BANZEL

## Products Affected

- Banzel
- Rufinamide

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 1 year of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BAVENCIO

**Products Affected**

- Bavencio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Gestational trophoblastic neoplasia, endometrial carcinoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For urothelial carcinoma, the requested drug will be used as either of the following: 1) maintenance therapy if there is no progression on first-line platinum-containing chemotherapy OR 2) subsequent therapy for any of the following: a) locally advanced or metastatic urothelial carcinoma, b) urothelial carcinoma of the bladder with muscle invasive local recurrence or persistent disease in a preserved bladder, c) urothelial carcinoma of the bladder with metastatic or local recurrence post cystectomy, d) recurrent primary carcinoma of the urethra, or e) urothelial carcinoma of the bladder with stage II-IV disease. For renal cell carcinoma: the disease is advanced, relapsed, or stage IV, AND the requested drug will be used in combination with axitinib as first-line therapy. For gestational trophoblastic neoplasia, the requested drug will be used for multiagent chemotherapy resistant disease when the patient meets either of the following: 1) high risk disease OR 2) has recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor). For Merkel cell carcinoma, the requested drug is used for metastatic disease. For endometrial carcinoma, 1) the requested drug will be used as second-line treatment, 2) the disease is recurrent or metastatic, AND 3) the disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BAXDELA

## Products Affected

- Baxdela

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | 14 days |
| **Other Criteria** | N/A |

# BELBUCA

## Products Affected

- Belbuca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe enough to require daily, around-the-clock, long-term treatment in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BELEODAQ

**Products Affected**

- Beleodaq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Adult T-cell leukemia/lymphoma, extranodal NK/T-cell lymphoma, hepatosplenic T-cell lymphoma, breast implant associated anaplastic large cell lymphoma (ALCL). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BENLYSTA

## Products Affected

- Benlysta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | For patients new to therapy: severe active central nervous system lupus. |
| **Required Medical Information** | For systemic lupus erythematosus (SLE): 1) patient is currently receiving a stable standard therapy regimen (e.g., corticosteroid, antimalarial, or NSAIDs) for SLE, OR 2) patient has experienced an intolerance or has a contraindication to standard therapy regimen for SLE. For lupus nephritis: 1) patient is currently receiving a stable standard therapy regimen (e.g., corticosteroid, cyclophosphamide, mycophenolate mofetil, or azathioprine) for lupus nephritis OR 2) patient has experienced an intolerance or has a contraindication to standard therapy regimen for lupus nephritis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BENZNIDAZOLE

## Products Affected

- Benznidazole

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Patient who has taken disulfiram within the last two weeks. |
| **Required Medical Information** | Chagas disease: patient has serologic evidence of Trypanosoma cruzi infection. |
| **Age Restrictions** | 2 to 12 years of age |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 2 months |
| **Other Criteria** | N/A |

# BEOVU

## Products Affected

- Beovu SOSY

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# BERINERT

**Products Affected**

- Berinert

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute angioedema attacks due to hereditary angioedema (HAE): Patient meets either of the following: 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the 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 b) the 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. |
| **Age Restrictions** | 5 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BESPONSA

## Products Affected

- Besponsa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For B-cell precursor acute lymphoblastic leukemia (ALL): The tumor is CD22-positive as confirmed by testing or analysis to identify the CD22 protein on the surface of the B-cell. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BESREMI

## Products Affected

- Besremi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BETASERON

## Products Affected

- Betaseron

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BEXAROTENE

## Products Affected

- Bexarotene CAPS
- Targretin CAPS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Mycosis fungoides (MF)/Sezary syndrome (SS), CD30-positive primary cutaneous anaplastic large cell lymphoma (ALCL), CD30-positive lymphomatoid papulosis (LyP) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BIMZELX

## Products Affected

- Bimzelx

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BLENREP

## Products Affected

- Blenrep

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For relapsed, refractory, or progressive multiple myeloma: Patient must have been treated with at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BLINCYTO

## Products Affected

- Blincyto

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL), one of the following criteria are met: 1) the requested drug is used as consolidation or maintenance therapy OR 2) the requested drug is used for relapsed or refractory disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# BOSENTAN

## Products Affected

- Bosentan
- Tracleer

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BOSULIF

**Products Affected**

- Bosulif

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Philadelphia chromosome positive B-cell acute lymphoblastic leukemia (Ph+ B-ALL), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L, AND 3) patient has experienced resistance or intolerance to imatinib or dasatinib. For B-ALL including patient who have received hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, and 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BOTOX

## Products Affected

- Botox

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Excessive salivation secondary to advanced Parkinson's disease, hemifacial spasm, chronic anal fissure, achalasia, spasmodic dysphonia (laryngeal dystonia), oromandibular dystonia, palmar hyperhidrosis, essential tremor, myofascial pain. |
| **Exclusion Criteria** | Cosmetic use. |
| **Required Medical Information** | For chronic migraine prophylaxis, initial treatment: patient experiences at least 15 headache days per month, and patient had an inadequate response, intolerance, or a contraindication to a calcitonin gene-related peptide (CGRP) inhibitor. For chronic migraine prophylaxis, continuation of treatment (after 2 injection cycles): More headache-free days per month since starting therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Chronic migraine, initial tx: 6 months, renewal: Plan Year. Plan Year for all other indications. |
| **Other Criteria** | N/A |

# BRAFTOVI

## Products Affected

- Braftovi CAPS 75MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Adjuvant systemic therapy for cutaneous melanoma, appendiceal adenocarcinoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For colorectal cancer (including appendiceal adenocarcinoma): 1) Tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used for either of the following: a) subsequent therapy for advanced or metastatic disease, b) primary treatment for unresectable metachronous metastases. For melanoma: 1) Tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with binimetinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BRISDELLE

## Products Affected

- Paroxetine

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BRIUMVI AET

## Products Affected

- Briumvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including relapsing-remitting disease, active secondary progressive disease, and clinically isolated syndrome]: Patient must have tried and failed or has a contraindication or intolerance to two of the following: brand Aubagio, Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone, brand Tecfidera, Vumerity (diroximel fumarate), Zeposia (ozanimod). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BRIVIACT

## Products Affected

- Briviact ORAL SOLN
- Briviact TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older). |
| **Age Restrictions** | 1 month of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BRIVIACT INJ

## Products Affected

- Briviact INJ

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older). |
| **Age Restrictions** | 1 month of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BRIXADI

## Products Affected

- Brixadi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Prescribed only for the treatment of pain |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BROMSITE AET

## Products Affected

- Bromfenac Sodium SOLN 0.075%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of postoperative inflammation and prevention of ocular pain in a patient undergoing cataract surgery: patient has experienced an intolerable adverse event to brand Bromsite caused by an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# BRONCHITOL

## Products Affected

- Bronchitol
- Bronchitol Tolerance Test

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BROVANA AET

## Products Affected

- Arformoterol Tartrate
- Brovana

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following: Breo Ellipta (fluticasone/vilanterol), fluticasone/salmeterol, Incruse Ellipta (umeclidinium), Anoro Ellipta (umeclidinium/vilanterol), Bevespi (glycopyrrolate/formoterol), Serevent Diskus (salmeterol), Trelegy Ellipta (fluticasone/umeclidinium/vilanterol), Wixela. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# BRUKINSA

## Products Affected

- Brukinsa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BUPRENORPHINE

## Products Affected

- Buprenorphine Hcl SUBL

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 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 a patient who is intolerant to naloxone. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BUPRENORPHINE PATCH

## Products Affected

- Buprenorphine PTWK
- Butrans

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe enough to require daily, around-the-clock, long-term treatment in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# BUTALBITAL AET

## Products Affected

- Allzital
- Ascomp/codeine
- Bupap TABS 300MG; 50MG
- Butalbital/acetaminophen CAPS
- Butalbital/acetaminophen TABS 300MG; 50MG, 325MG; 50MG
- Butalbital/acetaminophen/caffeine CAPS
- Butalbital/acetaminophen/caffeine TABS 325MG; 50MG; 40MG
- Butalbital/acetaminophen/caffeine/codeine
- Butalbital/aspirin/caffeine CAPS
- Butalbital/aspirin/caffeine/codeine
- Esgic
- Fioricet CAPS
- Fioricet/codeine CAPS 300MG; 50MG; 40MG; 30MG
- Tencon TABS 325MG; 50MG
- Zebutal CAPS 325MG; 50MG; 40MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) The prescriber must acknowledge the benefit of therapy with the requested drug outweighs the potential risks for the patient (Note: 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.) AND 2) the patient has experienced an inadequate treatment response or intolerance to a nonsteroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication to NSAIDs. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | This Prior Authorization only applies to patients 65 years of age or older. |

# BYDUREON

## Products Affected

- Bydureon Bcise

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 10 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | The Prior Authorization only applies to patients whose claim is not submitted with an ICD-10 code indicating a diagnosis of type 2 diabetes mellitus OR to patients who do not have a history of an antidiabetic drug (EXCLUDING glucagon-like peptide receptor agonists [GLP-1 RAs] and combination glucose-dependent insulinotropic polypeptide [GIP] and GLP-1 RAs). |

# BYETTA

## Products Affected

- Byetta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | The Prior Authorization only applies to patients whose claim is not submitted with an ICD-10 code indicating a diagnosis of type 2 diabetes mellitus OR to patients who do not have a history of an antidiabetic drug (EXCLUDING glucagon-like peptide receptor agonists [GLP-1 RAs] and combination glucose-dependent insulinotropic polypeptide [GIP] and GLP-1 RAs). |

# BYLVAY

## Products Affected

- Bylvay
- Bylvay (pellets)

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of pruritis in progressive familial intrahepatic cholestasis (PFIC) (initial requests): 1) diagnosis of PFIC has been confirmed by genetic testing, 2) the patient does not have PFIC type 2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3), 3) the patient does not have any other concomitant liver disease, AND 4) the patient has not received a liver transplant. For treatment of pruritis in PFIC (continuation requests): the patient has experienced benefit from therapy (for example, improvement in pruritis). For treatment of cholestatic pruritus with Alagille Syndrome (ALGS) (continuation): the patient has experienced benefit from therapy (for example, improvement in pruritis). |
| **Age Restrictions** | For PFIC: 3 months of age or older, For ALGS: 12 months of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hepatologist or gastroenterologist |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# BYOOVIZ

## Products Affected

- Byooviz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# CABLIVI

**Products Affected**

- Cablivi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acquired thrombotic thrombocytopenic purpura (aTTP): Initial course and treatment extension: Patient has not experienced more than 2 recurrences of aTTP while on the requested drug. For aTTP initial course: 1) the request is for treatment during the plasma exchange period and/or directly following the completion of plasma exchange (PE), 2) patient will receive or has received the requested drug with PE, 3) the requested drug will be given in combination with immunosuppressive therapy, and 4) patient will not receive the requested drug beyond 30 days from the cessation of PE unless the patient has documented persistent aTTP. For aTTP extension of therapy: 1) the request is for extension of therapy after the initial course of the requested drug (initial course: treatment with the requested drug during and 30 days after plasma exchange), 2) patient has documented signs of persistent underlying aTTP (example: severely reduced ADAMTS13 activity levels [less than 10%]), 3) the requested drug will be given in combination with immunosuppressive therapy, and 4) patient has not received a prior 28 day extension of therapy after the initial course of the requested drug for this course of treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial course: 60 days, Extension: 28 days |
| **Other Criteria** | N/A |

# CABOMETYX

**Products Affected**

- Cabometyx

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-small cell lung cancer, Ewing sarcoma, osteosarcoma, gastrointestinal stromal tumor, endometrial carcinoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For renal cell carcinoma: The disease is advanced, relapsed, or stage IV. For non-small cell lung cancer: 1) the disease is rearranged during transfection (RET) positive AND 2) the disease is recurrent, advanced, or metastatic. For hepatocellular carcinoma: the requested drug will be used as subsequent treatment. For gastrointestinal stromal tumor (GIST): The patient meets either of the following: 1) the disease is unresectable, recurrent/progressive, or metastatic AND the patient has failed a FDA-approved therapy (e.g., imatinib, sunitinib, regorafenib, ripretinib) OR 2) the requested drug will be used for palliation of symptoms if previously tolerated and effective. For Ewing sarcoma and osteosarcoma: the requested drug will be used as subsequent therapy. For differentiated thyroid cancer (DTC) (follicular, papillary, Hurthle cell): 1) The disease is locally advanced or metastatic disease, 2) the disease has progressed after a vascular endothelial growth factor receptor (VEGFR)- targeted therapy, AND 3) the patient is refractory to radioactive iodine therapy (RAI) or ineligible for RAI.For endometrial carcinoma: 1) the disease is recurrent or metastatic AND 2) the requested drug will be used as subsequent therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CALCIPOTRIENE

## Products Affected

- Calcipotriene CREA
- Calcipotriene FOAM
- Calcipotriene OINT
- Calcipotriene SOLN
- Calcipotriene/betamethasone Dipropionate
- Calcitrene
- Calcitriol OINT
- Enstilar
- Sorilux
- Taclonex SUSP
- Vectical

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Treatment of Psoriasis: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a topical steroid. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CALQUENCE

**Products Affected**

- Calquence

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Waldenstrom macroglobulinemia (lymphoplasmacytic lymphoma), marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, splenic marginal zone lymphoma) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug is being used for the treatment of relapsed, refractory, or progressive disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CAMBIA

## Products Affected

- Cambia
- Diclofenac Potassium PACK

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to diclofenac or any components of the requested drug. History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs). The requested drug will be used in the setting of coronary artery bypass graft (CABG) surgery. |
| **Required Medical Information** | 1) The patient has experienced an inadequate treatment response or intolerance to at least ONE of the following non-steroidal anti-inflammatory drugs (NSAIDs): a) ibuprofen, b) flurbiprofen, c) ketoprofen, d) naproxen AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least ONE triptan 5-HT1 agonist. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CAMZYOS

## Products Affected

- Camzyos

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For obstructive hypertropic cardiomyopathy: 1) before initiating therapy, patient has left ventricular ejection fraction (LVEF) of 55 percent or greater AND 2) patient has New York Heart Association (NYHA) class II-III symptoms. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CAPRELSA

## Products Affected

- Caprelsa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Differentiated thyroid carcinoma: papillary, follicular, and Hurthle cell. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CARAC

## Products Affected

- Carac
- Fluorouracil CREA 0.5%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Patients who are pregnant or may become pregnant. Patients with dihydropyrimidine dehydrogenase (DPD) enzyme deficiency. |
| **Required Medical Information** | If being used as part of a compounded product, all active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# CARBAGLU

## Products Affected

- Carbaglu
- Carglumic Acid

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For N-acetylglutamate synthase (NAGS) deficiency: Diagnosis of NAGS deficiency was confirmed by enzymatic, biochemical, or genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CAYSTON

## Products Affected

- Cayston

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of respiratory symptoms in cystic fibrosis patients: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of pseudomonas aeruginosa infection or colonization in the airways. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CEQUA

## Products Affected

- Cequa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) The patient has experienced an inadequate treatment response or intolerance to Restasis (cyclosporine 0.05 percent emulsion) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: Xiidra (lifitegrast), Miebo (perfluorohexyloctane). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CERDELGA

## Products Affected

- Cerdelga

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For type 1 Gaucher disease (GD1): 1) Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing, and 2) Patient's CYP2D6 metabolizer status has been established using an FDA-cleared test, and 3) Patient is a CYP2D6 extensive metabolizer, an intermediate metabolizer, or a poor metabolizer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CEREZYME

## Products Affected

- Cerezyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Type 2 Gaucher disease, Type 3 Gaucher disease. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Gaucher disease: Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CHANTIX AET

## Products Affected

- Varenicline Starting Month
- Varenicline Tartrate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | This Prior Authorization requirement applies after the patient has received a cumulative 24 weeks of therapy in a Plan Year. |

# CHENODAL AET

**Products Affected**

- Chenodal

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Contraindicated in the presence of known hepatocyte dysfunction or bile ductal abnormalities such as intrahepatic cholestasis, primary biliary cirrhosis or sclerosing cholangitis, a gallbladder confirmed as nonvisualizing after two consecutive single doses of dye, radiopaque stones, or gallstone complications or compelling reasons for gallbladder surgery including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary gastrointestinal fistula. Contraindicated in women who are or may become pregnant. |
| **Required Medical Information** | For radiolucent stones in a well-opacifying gallbladder, the patient must meet all of the following: 1) the patient has an increased surgical risk due to systemic disease or age, and 2) the patient must have tried and failed, or has a contraindication or intolerance to ursodiol, and 3) cumulative use with the requested drug will not exceed 24 months, and 4) documentation of start date of therapy is provided. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CHLORDIAZEPOXIDE - 65

## Products Affected

- Chlordiazepoxide Hcl CAPS 10MG, 5MG
- Chlordiazepoxide Hydrochloride CAPS 25MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications: the prescriber must acknowledge the benefit of therapy with the prescribed medication outweighs the potential risks for the patient. (Note: 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.) 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), or b) serotonin-norepinephrine reuptake inhibitors (SNRIs). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Short-term relief anxiety-preop apprehens and anx-1 mo, Anxiety Disorder-4 mo, Alc Withdrawal-PlanYR |
| **Other Criteria** | This Prior Authorization only applies to patients 65 years of age or older. |

# CHOLBAM

## Products Affected

- Cholbam

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For bile acid synthesis disorders due to single enzyme defects (SEDs) and adjunctive treatment of peroxisomal disorders (PDs): Diagnosis was confirmed by mass spectrometry or other biochemical or genetic testing. For bile acid synthesis disorders due to SEDs and adjunctive treatment of PDs, continuation of therapy: Patient has achieved and maintained improvement in liver function. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# CIBINQO

**Products Affected**

- Cibinqo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For atopic dermatitis (AD), continuation of therapy: Patient achieved or maintained positive clinical response. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 4 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# CIMERLI

## Products Affected

- Cimerli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# CIMZIA

## Products Affected

- Cimzia
- Cimzia Starter Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active Crohn's disease (new starts only): 1) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab) OR 2) the patient is currently pregnant and/or breastfeeding. For moderately to severely active rheumatoid arthritis (new starts only): 1) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release) OR 2) the patient is currently pregnant and/or breastfeeding. For active ankylosing spondylitis (new starts only): 1) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release) OR 2) the patient is currently pregnant and/or breastfeeding. For active non-radiographic axial spondyloarthritis (new starts only): 1) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Taltz (ixekizumab) OR 2) the patient is currently pregnant and/or breastfeeding. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | Plan Year |
| **Other Criteria** | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) the patient meets either of the following: a) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab) OR b) the patient is currently pregnant and/or breastfeeding. For active psoriatic arthritis (new starts only): 1) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release) OR 2) the patient is currently pregnant and/or breastfeeding. |

# CINQAIR

## Products Affected

- Cinqair

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Severe asthma, initial therapy: 1) Either a) Patient has baseline blood eosinophil count of at least 400 cells per microliter OR b) Patient is dependent on systemic corticosteroids, and 2) Patient has a history of severe asthma despite current treatment with both of the following medications: a) medium-to-high-dose inhaled corticosteroid and b) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. Severe asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CINRYZE

**Products Affected**

- Cinryze

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the prevention of acute angioedema attacks due to hereditary angioedema (HAE): Patient meets either of the following: 1) the patient has hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has hereditary angioedema with normal C1 inhibitor confirmed by laboratory testing and either of the following: a) 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 b) 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. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CINVANTI

## Products Affected

- Cinvanti

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# CITALOPRAM CAP AET

## Products Affected

- Citalopram Hydrobromide CAPS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has had a documented trial of one month each of both of the following (a and b): a) generic citalopram tablets AND b) one of the following: formulary generic antidepressant (other than citalopram tablets), Fetzima (levomilnacipran), or Trintellix (vortioxetine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CLOBAZAM

## Products Affected

- Clobazam
- Onfi SUSP
- Onfi TABS 10MG, 20MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Seizures associated with Dravet syndrome |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Seizures associated with Lennox-Gastaut syndrome (LGS): 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CLOMIPRAMINE

## Products Affected

- Anafranil
- Clomipramine Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Depression, panic disorder |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For obsessive-compulsive disorder (OCD) and panic disorder: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to any of the following: a serotonin and norepinephrine reuptake inhibitor (SNRI), a selective serotonin reuptake inhibitor (SSRI). For depression: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CLORAZEPATE

## Products Affected

- Clorazepate Dipotassium TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: 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.) 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). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Short-term relief anxiety-1 month, Anxiety Disorders-4 months, All other Diagnoses-Plan Year |
| **Other Criteria** | This Prior Authorization only applies to patients 65 years of age or older. |

# CLOZAPINE ODT

## Products Affected

- Clozapine Odt

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# COBENFY

## Products Affected

- Cobenfy CAPS 20MG; 50MG, 30MG; 125MG
- Cobenfy Starter Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# COLUMVI

## Products Affected

- Columvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# COLY-MYCIN

## Products Affected

- Colistimethate Sodium INJ
- Coly-mycin M

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug is being used intravenously (IV) or intramuscularly (IM). Administration will not be via nebulizer (Note: CMS endorsed compendia do not support inhalation/nebulization of colistimethate.). The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | Initial approval: 3 months. Renewal: Plan Year |
| **Other Criteria** | N/A |

# COMETRIQ

## Products Affected

- Cometriq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-small cell lung cancer (NSCLC), differentiated thyroid carcinoma: papillary, follicular, and Hurthle cell. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For NSCLC: The requested medication is used for NSCLC when the patient's disease expresses rearranged during transfection (RET) gene rearrangements. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# COPIKTRA

## Products Affected

- Copiktra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Hepatosplenic T-Cell lymphoma, breast implant-associated anaplastic large cell lymphoma (ALCL), peripheral T-Cell lymphoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), breast implant-associated anaplastic large cell lymphoma (ALCL), and peripheral T-Cell lymphoma: the patient has relapsed or refractory disease. For hepatosplenic T-Cell lymphoma: the patient has refractory disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CORTROPHIN

## Products Affected

- Cortrophin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the following diagnoses, patient has experienced an inadequate treatment response to a parenteral or an oral glucocorticoid (for ophthalmic diseases only, inadequate response to a trial of a topical ophthalmic glucocorticoid is also acceptable): 1) For rheumatic disorders (e.g., psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, acute gouty arthritis): The requested drug must be used as adjunctive treatment, 2) For nephrotic syndrome: the requested drug must be requested for induction of diuresis or for remission of proteinuria, 3) For multiple sclerosis (MS): patient has an acute exacerbation of MS, 4) Collagen diseases (e.g., systemic lupus erythematosus, dermatomyositis, or polymyositis), 5) Dermatologic diseases (e.g., severe erythema multiforme, Stevens-Johnson syndrome, severe psoriasis), 6) Ophthalmic diseases, acute or chronic (e.g., iritis, keratitis, optic neuritis), 7) Symptomatic sarcoidosis, 8) Allergic states (e.g., serum sickness, atopic dermatitis). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | MS exacerbation: 3 wks. Allergic states: 1 month. All other diagnoses: 3 months |
| **Other Criteria** | N/A |

# COSENTYX

## Products Affected

- Cosentyx
- Cosentyx Sensoready Pen
- Cosentyx Unoready

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab). For active ankylosing spondylitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Taltz (ixekizumab). For an adult with active psoriatic arthritis (PsA) (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | Plan Year |
| **Other Criteria** | For moderate to severe hidradenitis suppurativa (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf). |

# COTELLIC

**Products Affected**

- Cotellic

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Central nervous system (CNS) cancer (i.e., glioma, glioblastoma, astrocytoma, oligodendroglioma), adjuvant systemic therapy for cutaneous melanoma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For central nervous system (CNS) cancer (i.e., glioma, glioblastoma, astrocytoma, oligodendroglioma): 1) The tumor is positive for BRAF V600E activating mutation, AND 2) The requested drug will be used in combination with vemurafenib. For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used in combination with vemurafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CRINONE

## Products Affected

- Crinone

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Prophylaxis for premature birth in women with a short cervix |
| **Exclusion Criteria** | Prescribed to promote fertility |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CRYSVITA

## Products Affected

- Crysvita

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CUTAQUIG

## Products Affected

- Cutaquig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# CUVITRU

## Products Affected

- Cuvitru

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# CUVRIOR

**Products Affected**

- Cuvrior

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CYCLOPHOSPHAMIDE ORAL

## Products Affected

- Cyclophosphamide CAPS
- Cyclophosphamide TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# CYCLOSET AET

**Products Affected**

- Cycloset

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Patients with syncopal migraine. Lactating patients. Postpartum patients. |
| **Required Medical Information** | Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to metformin or metformin combination products. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CYRAMZA

**Products Affected**

- Cyramza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Esophageal adenocarcinoma, recurrent non-small cell lung cancer (NSCLC), appendiceal adenocarcinoma, pleural mesothelioma, pericardial mesothelioma, tunica vaginalis testis mesothelioma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For colorectal cancer and appendiceal adenocarcinoma: patient has advanced or metastatic disease. For NSCLC: patient has recurrent, advanced, or metastatic disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CYSTAGON

## Products Affected

- Cystagon

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For nephropathic cystinosis: Diagnosis was confirmed by ANY of the following: 1) the presence of increased cystine concentration in leukocytes, OR 2) genetic testing, OR 3) demonstration of corneal cystine crystals by slit lamp examination. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# CYSTARAN

## Products Affected

- Cystadrops
- Cystaran

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cystinosis: 1) Diagnosis was confirmed by ANY of the following: a) the presence of increased cystine concentration in leukocytes, OR b) genetic testing, OR c) demonstration of corneal cystine crystals by slit lamp examination, AND 2) the patient has corneal cystine crystal accumulation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DALFAMPRIDINE

## Products Affected

- Ampyra
- Dalfampridine Er

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For multiple sclerosis, patient must meet the following: For new starts, prior to initiating therapy, patient demonstrates sustained walking impairment. For continuation of therapy: patient must have experienced an improvement in walking speed OR other objective measure of walking ability since starting the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DAPAGLIFLOZIN AET

**Products Affected**

- Dapagliflozin Propanediol

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications: patient has experienced an intolerable adverse event to brand Farxiga caused by an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DAPAGLIFLOZIN-METFORMIN AET

**Products Affected**

- Dapagliflozin Propanediol/metformin Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications: patient has experienced an intolerable adverse event to brand Xigduo XR caused by an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DARAPRIM

## Products Affected

- Daraprim
- Pyrimethamine TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Toxoplasmosis prophylaxis, Pneumocystis jirovecii pneumonia prophylaxis, cystoisosporiasis treatment and secondary prophylaxis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary toxoplasmosis prophylaxis and Pneumocystis jirovecii pneumonia (PCP) prophylaxis: 1) The patient has experienced an intolerance or has a contraindication to trimethoprim-sulfamethoxazole (TMP-SMX) AND 2) The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 3 months. For secondary toxoplasmosis prophylaxis: The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 6 months. For cystoisosporiasis treatment: The patient has experienced an intolerance or has a contraindication to TMP-SMX. For secondary cystoisosporiasis prophylaxis: 1) The patient has experienced an intolerance or has a contraindication to TMP-SMX AND 2) The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 6 months. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Congen toxo tx: Plan Yr. Acqu toxo tx, prim toxo ppx, PCP ppx: 3mo. Sec toxo ppx, cysto tx/ppx: 6mo |
| **Other Criteria** | N/A |

# DARZALEX

## Products Affected

- Darzalex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Relapsed/refractory systemic light chain amyloidosis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DARZALEX FASPRO

**Products Affected**

- Darzalex Faspro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DAURISMO

## Products Affected

- Daurismo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Post induction therapy following response to previous therapy with the same regimen for acute myeloid leukemia (AML). Relapsed/refractory AML as a component of repeating the initial successful induction regimen. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute myeloid leukemia: 1) the requested drug must be used in combination with cytarabine, 2) the patient is 75 years of age or older OR has comorbidities that preclude intensive chemotherapy, AND 3) the requested drug will be used as treatment for induction therapy, post-induction therapy, or relapsed or refractory disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DAYBUE

**Products Affected**

- Daybue

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DEFERASIROX

## Products Affected

- Deferasirox
- Exjade
- Jadenu
- Jadenu Sprinkle

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic iron overload due to blood transfusions: pretreatment serum ferritin level is greater than 1000 mcg/L. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DEMSER

## Products Affected

- Demser
- Metyrosine

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to an alpha-adrenergic antagonist. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DESVENLAFAXINE

## Products Affected

- Desvenlafaxine Er

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Major Depressive Disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DHE NASAL

## Products Affected

- Dihydroergotamine Mesylate NASAL SOLN
- Migranal
- Trudhesa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **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** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DIACOMIT

## Products Affected

- Diacomit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 6 months of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DIAZEPAM AET

## Products Affected

- Diazepam CONC
- Diazepam INJ 5MG/ML
- Diazepam SOLN 5MG/5ML
- Diazepam TABS
- Diazepam Intensol
- Valium TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: 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.) 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). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Short-term relief anx-1 mo, skeletal muscle spasm-3 mo, Anx Disorders-4 mo, Other Diagnoses-PlanYR |
| **Other Criteria** | This Prior Authorization only applies to patients 65 years of age or older. |

# DICLOFENAC 1.5% SOL

## Products Affected

- Diclofenac Sodium EXTERNAL SOLN 1.5%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DICLOFENAC 2% SOL

## Products Affected

- Diclofenac Sodium EXTERNAL SOLN 2%
- Pennsaid SOLN 2%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For osteoarthritis of the knee(s): Patient has experienced an inadequate treatment response or intolerance to diclofenac sodium 1.5% topical solution. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DICLOFENAC 3% GEL

**Products Affected**

- Diclofenac Sodium GEL 3%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following: A) imiquimod 5 percent cream, B) fluorouracil cream or solution. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# DIMETHYL FUMARATE AET

## Products Affected

- Dimethyl Fumarate CPDR
- Dimethyl Fumarate Starterpack CDPK 0

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease]: Patient has experienced an intolerance to brand Tecfidera due to an adverse event (e.g., rash, nausea, vomiting, anaphylaxis) caused by an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DOJOLVI

**Products Affected**

- Dojolvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For long-chain fatty acid oxidation disorders (LC-FAOD): At least two of the following diagnostic criteria are met: a) disease-specific elevation of acylcarnitine (e.g., C16 and/or C18:1 for CPT2 deficiency, C16-OH and/or C18 and other acylcarnitines for LCHAD and TFP deficiency, C14:1 and/or other long-chain acylcarnitines for VLCAD deficiency) on a newborn blood spot or in plasma, b) low enzyme activity in cultured fibroblasts, c) one or more known pathogenic mutations (e.g., CPT1A, SLC25A20, CPT2, ACADVL, HADHA, HADHB). For LC-FAOD, continuation of therapy: Patient is experiencing benefit from therapy (e.g., improvement in muscle symptoms and/or exercise tolerance). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DOPTELET

## Products Affected

- Doptelet

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For thrombocytopenia in patients with chronic liver disease: Untransfused platelet count prior to a scheduled procedure is less than 50,000/mcL. For chronic immune thrombocytopenia (ITP): 1) For new starts: a) Patient has had an inadequate response or is intolerant to prior therapy such as corticosteroids or immunoglobulins, AND b) Untransfused platelet count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000 to 50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes patient to trauma). 2) For continuation of therapy, platelet count response to the requested drug: a) Current platelet count is less than or equal to 200,000/mcL OR b) Current platelet count is greater than 200,000/mcL and less than or equal to 400,000/mcL and dosing will be adjusted to a platelet count sufficient to avoid clinically important bleeding. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Chronic liver disease: 1 month, ITP initial: 6 months, ITP reauthorization: Plan Year |
| **Other Criteria** | N/A |

# DRIZALMA

## Products Affected

- Drizalma Sprinkle

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Cancer pain, chemotherapy-induced neuropathic pain |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) The patient has tried duloxetine capsules OR 2) The patient is unable to take duloxetine capsules for any reason (e.g., difficulty swallowing capsules, requires nasogastric administration). |
| **Age Restrictions** | Generalized Anxiety Disorder - 7 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DRONABINOL

## Products Affected

- Dronabinol
- Marinol
- Syndros

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For nausea and vomiting associated with cancer chemotherapy: The patient has experienced an inadequate treatment response, intolerance, or contraindication to one oral 5-HT3 receptor antagonist. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# DUEXIS

## Products Affected

- Duexis
- Ibuprofen/famotidine

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response or intolerance to two different regimens containing any combination of a nonsteroidal anti-inflammatory drug (NSAID) and an acid blocker from any of the following drug classes: H2-receptor antagonist (H2RA), proton pump inhibitor (PPI). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DUOBRII

## Products Affected

- Duobrii

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For plaque psoriasis: the patient experienced an inadequate treatment response or intolerance to a topical corticosteroid. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DUPIXENT

## Products Affected

- Dupixent

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For atopic dermatitis (AD), initial therapy: 1) Patient has moderate-to-severe disease, AND 2) Patient has had an inadequate treatment response to either a topical corticosteroid or a topical calcineurin inhibitor, OR topical corticosteroids and topical calcineurin inhibitors are not advisable for the patient. For AD, continuation of therapy: Patient achieved or maintained positive clinical response. For oral corticosteroid dependent asthma, initial therapy: Patient has inadequate asthma control despite current treatment with both of the following medications: 1) High-dose inhaled corticosteroid AND 2) Additional controller (i.e., long acting beta2-agonist, long-acting, muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For moderate-to-severe asthma, initial therapy: Patient has a baseline blood eosinophil count of at least 150 cells per microliter and their asthma remains inadequately controlled despite current treatment with both of the following medications: 1) Medium-to-high-dose inhaled corticosteroid, AND 2) Additional controller (i.e., long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For chronic rhinosinusitis with nasal polyposis (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) Patient has experienced an inadequate treatment response to Xhance (fluticasone). |
| **Age Restrictions** | Atopic Dermatitis: 6 months of age or older, Asthma: 6 years of age or older, Chronic Rhinosinusitis with Nasal Polyposis and Prurigo Nodularis: 18 years of age or older, Eosinophilic Esophagitis: 1 year of age or older |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | AD, initial: 4 months, PN, initial: 6 months, All others: Plan Year |
| **Other Criteria** | For eosinophilic esophagitis (EoE), initial therapy: 1) Diagnosis has been confirmed by esophageal biopsy, AND 2) Patient weighs at least 15 kilograms, AND 3) Patient experienced an inadequate treatment response, intolerance, or patient has a contraindication to a topical corticosteroid (e.g., fluticasone propionate or budesonide). For EoE, continuation of therapy: Patient achieved or maintained a positive clinical response. For prurigo nodularis (PN), initial therapy: Patient has had an inadequate treatment response to a topical corticosteroid OR topical corticosteroids are not advisable for the patient. For PN, continuation of therapy: Patient achieved or maintained a positive clinical response. |

# DURYSTA

## Products Affected

- Durysta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DUVYZAT

**Products Affected**

- Duvyzat

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of Duchenne muscular dystrophy (DMD): The diagnosis was confirmed by genetic testing identifying a disease-causing mutation of the DMD gene. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# DYCLOPRO

## Products Affected

- Dyclopro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# DYSPORT

## Products Affected

- Dysport

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Blepharospasm. |
| **Exclusion Criteria** | Cosmetic use. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EGRIFTA

## Products Affected

- Egrifta Sv

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Use for weight loss |
| **Required Medical Information** | For human immunodeficiency virus (HIV)-infected patients with lipodystrophy: Patient is receiving anti-retroviral therapy. For patients who have received at least 6 months of the requested drug: Patient has demonstrated clear clinical improvement from baseline that is supported by a waist circumference measurement or computed tomography (CT) scan. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist or endocrinologist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# ELAPRASE

## Products Affected

- Elaprase

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For mucopolysaccharidosis II (MPS II): Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of iduronate 2-sulfatase (IDS) enzyme activity or by genetic testing. |
| **Age Restrictions** | 16 months of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ELELYSO

## Products Affected

- Elelyso

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For type 1 Gaucher disease: Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ELFABRIO

## Products Affected

- Elfabrio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient meets ANY of the following: 1) Diagnosis of Fabry disease was confirmed by an enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity or by genetic testing OR 2) The patient is a symptomatic obligate carrier. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ELIGARD

## Products Affected

- Eligard

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent androgen receptor positive salivary gland tumors |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ELREXFIO

## Products Affected

- Elrexfio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ELYXYB

**Products Affected**

- Elyxyb

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to celecoxib or any components of the requested drug. History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs). Allergic-type reactions to sulfonamides. The requested drug will be used in the setting of coronary artery bypass graft (CABG) surgery. |
| **Required Medical Information** | 1) The patient has experienced an inadequate treatment response or intolerance to at least ONE of the following non-steroidal anti-inflammatory drugs (NSAIDs): a) ibuprofen, b) flurbiprofen, c) ketoprofen, d) naproxen AND 2) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to at least ONE triptan 5-HT1 agonist. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EMFLAZA

## Products Affected

- Deflazacort
- Emflaza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Duchenne muscular dystrophy (DMD): 1) The diagnosis of Duchenne muscular dystrophy (DMD) was confirmed by genetic testing identifying a disease-causing mutation of the DMD gene AND 2) The patient has tried prednisone and experienced unmanageable and clinically significant weight gain/obesity or psychiatric/behavioral issues such as abnormal behavior, aggression, or irritability. |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EMGALITY

## Products Affected

- Emgality

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants. For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug, and the patient had a reduction in migraine days per month from baseline. For episodic cluster headache, initial: The patient experienced an inadequate treatment response, intolerance, or contraindication to a triptan 5-HT1 receptor agonist. For episodic cluster headache, continuation: The patient received the requested drug for at least 3 weeks of treatment and had a reduction in weekly cluster headache attack frequency from baseline. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 3 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# EMPAVELI

**Products Affected**

- Empaveli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For paroxysmal nocturnal hemoglobinuria (PNH) (initial): 1) the diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by either: a) at least 5% PNH cells or b) at least 51% of GPI-AP deficient polymorphonuclear (PMN) cells AND 2) flow cytometry is used to demonstrate GPI-AP deficiency. For PNH (continuation of therapy): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) the patient has demonstrated a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | PNH initial: 6 months, PNH continuation: Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# EMPLICITI

## Products Affected

- Empliciti

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For multiple myeloma: Patient must have been treated with at least one prior therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EMSAM

## Products Affected

- Emsam

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Major Depressive Disorder (MDD): 1) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion OR 2) The patient is unable to swallow oral formulations. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ENBREL

## Products Affected

- Enbrel INJ 25MG/0.5ML, 50MG/ML
- Enbrel Mini
- Enbrel Sureclick

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Hidradenitis suppurativa, non-radiographic axial spondyloarthritis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis. For hidradenitis suppurativa (new starts only): patient has severe, refractory disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ENDARI

## Products Affected

- Endari
- L-glutamine PACK

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 5 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ENHERTU

## Products Affected

- Enhertu

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma), recurrent, locally advanced, or metastatic HER2-positive esophageal adenocarcinoma, recurrent HER2-positive gastric or esophagogastric junction adenocarcinoma, brain metastases in patients with HER2-positive breast cancer. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# ENJAYMO

**Products Affected**

- Enjaymo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cold agglutinin disease (continuation of therapy): patient achieved or maintained a positive clinical response (e.g., improvement in hemoglobin levels, markers of hemolysis [e.g., bilirubin, haptoglobin, lactate dehydrogenase [LDH], reticulocyte count], and a reduction in blood transfusions). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# ENSPRYNG

**Products Affected**

- Enspryng

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ENTADFI

## Products Affected

- Entadfi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For benign prostatic hyperplasia (BPH) in a patient with an enlarged prostate: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to combination therapy with a formulary alpha-blocker and finasteride AND 2) The patient has not already received 26 weeks of treatment with the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 26 weeks |
| **Other Criteria** | N/A |

# ENTYVIO

## Products Affected

- Entyvio
- Entyvio Pen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EOHILIA

## Products Affected

- Eohilia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For eosinophilic esophagitis (EoE): 1) Diagnosis has been confirmed by esophageal biopsy characterized by greater than or equal to 15 intraepithelial esophageal eosinophils per high power field, AND 2) The patient is exhibiting clinical manifestations of the disease (for example, dysphagia). |
| **Age Restrictions** | 11 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, allergist, or immunologist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# EPCLUSA

## Products Affected

- Epclusa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD-IDSA guidance |
| **Other Criteria** | N/A |

# EPIDIOLEX

## Products Affected

- Epidiolex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 1 year of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EPKINLY

## Products Affected

- Epkinly

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EPO

## Products Affected

- Procrit
- Retacrit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Anemia due to myelodysplastic syndromes (MDS), anemia in rheumatoid arthritis (RA), anemia due to hepatitis C treatment (ribavirin in combination with either interferon alfa or peginterferon alfa) |
| **Exclusion Criteria** | Patients receiving chemotherapy with curative intent. Patients with myeloid cancer. |
| **Required Medical Information** | Requirements regarding hemoglobin (Hgb) values exclude values due to a recent transfusion. For initial approval: 1) for all uses except anemia due to chemotherapy or myelodysplastic syndrome (MDS): patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%), AND 2) for all uses except surgery: pretreatment (no erythropoietin treatment in previous month) Hgb is less than 10 g/dL, AND 3) for MDS: pretreatment serum erythropoietin level is 500 international units/L or less. For reauthorizations (patient received erythropoietin treatment in previous month) in all uses except surgery: 1) patient has received at least 12 weeks of erythropoietin therapy, AND 2) patient responded to erythropoietin therapy, AND 3) current Hgb is less than 12 g/dL, AND 4) for all uses except anemia due to chemotherapy or MDS: patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 16 weeks |
| **Other Criteria** | Coverage includes use in anemia in patients whose religious beliefs forbid blood transfusions. Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual (e.g., used for treatment of anemia for a patient with chronic renal failure who is undergoing dialysis, or furnished from physician's supply incident to a physician service). |

# EPOGEN AET

**Products Affected**

- Epogen INJ 10000UNIT/ML, 20000UNIT/ML, 2000UNIT/ML, 3000UNIT/ML, 4000UNIT/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Anemia due to myelodysplastic syndromes (MDS), anemia in rheumatoid arthritis (RA), anemia due to hepatitis C treatment (ribavirin in combination with either interferon alfa or peginterferon alfa). |
| **Exclusion Criteria** | Patients receiving chemotherapy with curative intent. Patients with myeloid cancer. |
| **Required Medical Information** | Patient must have experienced an inadequate treatment response or intolerance to Procrit (epoetin alfa). Requirements regarding hemoglobin (Hgb) values exclude values due to a recent transfusion. For initial approval: 1) for all uses except anemia due to chemotherapy or myelodysplastic syndrome (MDS): patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%), AND 2) for all uses except surgery: pretreatment (no erythropoietin treatment in previous month) Hgb is less than 10 g/dL AND 3) for MDS: pretreatment serum erythropoietin level is 500 international units/L or less. For reauthorizations (patient received erythropoietin treatment in previous month) in all uses except surgery: 1) patient has received at least 12 weeks of erythropoietin therapy, AND 2) patient responded to erythropoietin therapy, AND 3) current Hgb is less than 12 g/dL, AND 4) for all uses except anemia due to chemotherapy or MDS: patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 16 weeks |

| | |
|---|---|
| **Other Criteria** | Coverage includes use in anemia in patients whose religious beliefs forbid blood transfusions. Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual (e.g., used for treatment of anemia for a patient with chronic renal failure who is undergoing dialysis, or furnished from physician's supply incident to a physician service). |

# EPRONTIA

## Products Affected

- Eprontia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1)The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older). For monotherapy treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response or intolerance to topiramate tablets or capsules, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) If the patient is 6 years of age or older, the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Spritam. For the preventative treatment of migraines: 1) The patient has experienced an inadequate treatment response or intolerance to topiramate tablets or capsules, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| **Age Restrictions** | Epilepsy: 2 years of age or older, Migraine: 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EPSOLAY

## Products Affected

- Epsolay

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of inflammatory lesions of rosacea: 1) the patient has experienced an inadequate treatment response or intolerance to topical metronidazole or topical azelaic acid 15 percent OR 2) the patient has a contraindication that would prohibit a trial of topical metronidazole and topical azelaic acid 15 percent. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ERAXIS AET

## Products Affected

- Eraxis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For esophageal candidiasis: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to fluconazole and voriconazole. |
| **Age Restrictions** | For candidemia and other forms of Candida infections (intra-abdominal abscess and peritonitis): 1 month of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist. |
| **Coverage Duration** | 6 weeks |
| **Other Criteria** | N/A |

# ERBITUX

## Products Affected

- Erbitux

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Occult primary head and neck cancer, penile cancer, squamous cell skin cancer, non-small cell lung cancer, appendiceal adenocarcinoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For colorectal cancer: 1) Tumor is negative (wild-type) for RAS (KRAS and NRAS) mutations, and 2) Patient has not previously experienced clinical failure on panitumumab, and 3) If tumor has a BRAF V600E mutation, the requested drug is used in combination with encorafenib. For squamous cell skin cancer, patient has incompletely resected regional disease or inoperable, recurrent, or metastatic disease. For penile cancer, patient has metastatic disease. For non-small cell lung cancer, patient meets both of the following: 1) Patient has a known sensitizing epidermal growth factor receptor (EGFR) mutation, and 2) The requested drug is used following disease progression on EGFR tyrosine kinase inhibitor therapy (e.g., afatinib, erlotinib, gefitinib). For appendiceal adenocarcinoma: 1) Disease is BRAF V600E mutation positive and 2) The requested drug will be used in combination with encorafenib. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ERGOTAMINE

## Products Affected

- Ergotamine Tartrate/caffeine
- Migergot

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **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 agonist. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ERIVEDGE

## Products Affected

- Erivedge

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Adult medulloblastoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For adult medulloblastoma: patient has received prior systemic therapy AND has tumor(s) with mutations in the sonic hedgehog pathway. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ERLEADA

## Products Affected

- Erleada

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ERLOTINIB

## Products Affected

- Erlotinib Hydrochloride TABS
- Tarceva

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent non-small cell lung cancer (NSCLC), recurrent chordoma, relapsed or stage IV renal cell carcinoma (RCC), brain metastases from non-small cell lung cancer (NSCLC), recurrent pancreatic cancer. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For NSCLC (including brain metastases from NSCLC): 1) the disease is recurrent, advanced, or metastatic and 2) the patient has sensitizing EGFR mutation-positive disease. For pancreatic cancer: the disease is locally advanced, unresectable, recurrent, or metastatic. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ESBRIET

## Products Affected

- Esbriet
- Pirfenidone

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For idiopathic pulmonary fibrosis (new starts only): 1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern, OR 2) HRCT study of the chest reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported either by a lung biopsy or by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EVENITY AET

## Products Affected

- Evenity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Patients who have had a myocardial infarction or stroke within the preceding year. |
| **Required Medical Information** | For postmenopausal osteoporosis: 1) patient meets ANY of the following: a) history of fragility fracture, OR b) pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment Fracture Risk Assessment Tool (FRAX) fracture probability, AND 2) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate, OR patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: teriparatide, Tymlos (abaloparatide), or Prolia (denosumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months lifetime total |
| **Other Criteria** | Patient has high Fracture Risk Assessment Tool (FRAX) fracture probability if the 10 year probability is either greater than or equal to 20 percent for any major osteoporotic fracture or greater than or equal to 3 percent for hip fracture. The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day. |

# EVEROLIMUS

## Products Affected

- Afinitor
- Afinitor Disperz
- Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG
- Everolimus TBSO
- Torpenz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Classic Hodgkin lymphoma, thymomas and thymic carcinomas, previously treated Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, soft tissue sarcoma (perivascular epithelioid cell tumors (PEComa) and lymphangioleiomyomatosis subtypes), gastrointestinal stromal tumors, neuroendocrine tumors of the thymus, well differentiated grade 3 neuroendocrine tumors, thyroid carcinoma (papillary, Hurthle cell, and follicular), endometrial carcinoma, histiocytic neoplasms (Rosai-Dorfman Disease, Erdheim-Chester Disease, Langerhans Cell Histiocytosis) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For breast cancer: 1) The disease is recurrent unresectable, advanced, or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, AND 2) The requested drug is prescribed in combination with exemestane, fulvestrant, or tamoxifen, AND 3) The requested drug is used for subsequent treatment.<br>For renal cell carcinoma: The disease is relapsed, advanced, or stage IV.<br>For subependymal giant cell astrocytoma (SEGA): The requested drug is given as adjuvant treatment. For gastrointestinal stromal tumor: The disease is recurrent/progressive, unresectable, or metastatic AND the patient failed an FDA-approved therapy (e.g., imatinib, sunitinib, regorafenib, ripretinib). For symptomatic or relapsed/refractory Erdheim-Chester Disease (ECD), symptomatic or relapsed/refractory Rosai-Dorfman Disease, and Langerhans Cell Histiocytosis (LCH): the patient must have a phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha (PIK3CA) mutation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EVKEEZA

## Products Affected

- Evkeeza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For initiation of therapy (tx) to treat homozygous familial hypercholesterolemia (HoFH), patient (pt) must meet ALL of the following: A) Diagnosis of HoFH confirmed by one of the following: 1) Genetic testing to confirm two mutant alleles at low-density lipoprotein receptor (LDLR), apolipoprotein B (ApoB), proprotein convertase subtilisin/kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus OR 2) History of an untreated low-density lipoprotein-cholesterol (LDL-C) greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL and either of the following: a) Presence of cutaneous or tendinous xanthomas before the age of 10 years, or b) An untreated LDL-C level greater than or equal to 190 mg/dL in both parents, which is consistent with heterozygous familial hypercholesterolemia (HeFH), AND B) If the pt is 7 years of age or older prior to initiation of treatment, pt is currently receiving treatment with a high-intensity statin at a maximally tolerated dose or at the maximum dose approved by the Food and Drug Administration (FDA) unless the pt is statin intolerant or has a contraindication to statin tx, AND C) If the pt is 10 years of age or older prior to initiation of treatment, pt is currently receiving treatment with a PCSK9-directed tx at a maximally tolerated dose or at the maximum dose approved by the FDA unless the pt has experienced an intolerance or has a contraindication to all PCSK9-directed therapies, AND D) Prior to initiation of treatment, pt is/was experiencing an inadequate response to lipid-lowering tx as indicated by a treated LDL-C greater than 100 mg/dL (or greater than 70 mg/dL with clinical atherosclerotic cardiovascular disease), AND E) Pt will continue to receive concomitant lipid lowering tx. For renewal of tx to treat HoFH: A) Pt meets all initial criteria, AND B) Has responded to tx as demonstrated by a reduction in LDL-C from baseline, AND C) Is receiving concomitant lipid lowering tx. |
| **Age Restrictions** | 5 years of age or older |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EVRYSDI

## Products Affected

- Evrysdi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For spinal muscular atrophy (SMA) initial therapy, patient meets all of the following: 1) Patient has type 1, type 2, or type 3 SMA, and 2) Patient is not dependent on permanent ventilation. For SMA continuation of therapy, patient meets all of the following: 1) Patient has type 1, type 2, or type 3 SMA, AND 2) Patient has experienced clinically significant functional improvement or maintenance of muscle function. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a physician who specializes in spinal muscular atrophy |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EXKIVITY

## Products Affected

- Exkivity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EXONDYS 51

## Products Affected

- Exondys 51

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EXTAVIA AET

## Products Affected

- Extavia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease]: Patient must have tried and failed or has a contraindication or intolerance to two of the following: brand Aubagio, Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone, brand Tecfidera, Vumerity (diroximel fumarate), Zeposia (ozanimod). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# EYLEA

## Products Affected

- Eylea

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# EYLEA HD

## Products Affected

- Eylea Hd

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# FABHALTA

## Products Affected

- Fabhalta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For paroxysmal nocturnal hemoglobinuria (PNH) (initial): 1) the diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) AND 2) flow cytometry is used to demonstrate GPI-AP deficiency. For PNH (continuation): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) the patient has demonstrated a positive response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# FABRAZYME

## Products Affected

- Fabrazyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Fabry disease, the patient meets ANY of the following: 1) diagnosis of Fabry disease was confirmed by an enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity or by genetic testing, OR 2) the patient is a symptomatic obligate carrier. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FANAPT

## Products Affected

- Fanapt
- Fanapt Titration Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. For acute treatment of manic or mixed episodes associated with bipolar I disorder: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to brand Vraylar. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FASENRA

## Products Affected

- Fasenra
- Fasenra Pen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Severe asthma, initial therapy: 1) Either a) Patient has baseline blood eosinophil count of at least 150 cells per microliter OR b) Patient is dependent on systemic corticosteroids, and 2) Patient has a history of severe asthma despite current treatment with both of the following medications: a) medium-to-high-dose inhaled corticosteroid and b) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. Severe asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FENSOLVI

## Products Affected

- Fensolvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For central precocious puberty (CPP): Patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, AND 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, AND 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients. |
| **Age Restrictions** | CPP: Patient must be less than 12 years old if female and less than 13 years old if male. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FENTANYL PATCH

## Products Affected

- Fentanyl PT72

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe enough to require daily, around-the-clock, long-term treatment in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FERRIPROX

## Products Affected

- Deferiprone
- Ferriprox
- Ferriprox Twice-a-day

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient's transfusional iron overload is not due to myelodysplastic syndrome or Diamond Blackfan anemia. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FETZIMA

## Products Affected

- Fetzima
- Fetzima Titration Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For major depressive disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FILGRASTIM

## Products Affected

- Nivestym

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Neutropenia in myelodysplastic syndromes (MDS), agranulocytosis, neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia, neutropenia related to renal transplantation |
| **Exclusion Criteria** | Use of the requested product within 24 hours prior to or following chemotherapy. |
| **Required Medical Information** | For prophylaxis or treatment of myelosuppressive chemotherapy-induced febrile neutropenia (FN), patient must meet all of the following: 1) Patient has a solid tumor or non-myeloid cancer AND 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# FILSPARI

## Products Affected

- Filspari

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For reduction of proteinuria in patients with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression: 1) The patient had an inadequate response to therapy with a maximally tolerated dose of a renin-angiotensin system (RAS) inhibitor (e.g., angiotensin-converting enzyme [ACE] inhibitor or angiotensin-receptor blocker [ARB]) OR 2) The patient experienced an intolerance or has a contraindication to RAS inhibitors. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FILSUVEZ

## Products Affected

- Filsuvez

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will not be administered to wound(s) that are currently healed. |
| **Age Restrictions** | 6 months of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist or wound care specialist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FINTEPLA

## Products Affected

- Fintepla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FIRDAPSE

## Products Affected

- Firdapse

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | History of seizures |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FIRMAGON

## Products Affected

- Firmagon INJ 120MG/VIAL, 80MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FLECTOR AET

## Products Affected

- Diclofenac Epolamine
- Flector

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs). For treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery. |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two generic oral nonsteroidal anti-inflammatory drugs (NSAIDs). |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# FLEQSUVY

## Products Affected

- Baclofen SUSP
- Fleqsuvy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient is unable to take oral solid dosage forms for any reason (e.g., difficulty swallowing tablets or capsules, requires administration via feeding tube). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FLUCYTOSINE

## Products Affected

- Ancobon
- Flucytosine CAPS 250MG, 500MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 weeks |
| **Other Criteria** | N/A |

# FLUOROURACIL

## Products Affected

- Efudex CREA
- Fluorouracil CREA 5%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Patients who are pregnant or may become pregnant. |
| **Required Medical Information** | Applies to new starts only. If being used as part of a compounded product, all active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# FLUTICASONE FUROATE AND VILANTEROL AET

## Products Affected

- Fluticasone Furoate/vilanterol Ellipta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of asthma and maintenance treatment of chronic obstructive pulmonary disease (COPD): patient has experienced an intolerance to brand Breo Ellipta due to an adverse event (e.g., rash, nausea, vomiting, anaphylaxis) caused by an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FLUTICASONE PROPIONATE HFA AET

## Products Affected

- Fluticasone Propionate Diskus
- Fluticasone Propionate Hfa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Eosinophilic esophagitis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For maintenance treatment of asthma: patient has experienced an intolerance to brand Flovent or Arnuity Ellipta. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FORM ALT PA METFORMIN

## Products Affected

- Metformin Hydrochloride TABS 625MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an intolerance, caused by an inactive ingredient, to one other formulary product such as metformin immediate-release. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FORM ALT PA TOPICAL

## Products Affected

- Bruselix GEL
- Lidotral GEL 3.88%
- Lidotral LIQD
- Lidotral SOLN
- Lidotral + Hydrocortisone CREA
- Mycozyl Hc

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an intolerance to one other formulary product. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FORM ALT PA TOPICAL STEROIDS

## Products Affected

- Hydroxym CREA

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an intolerance to one other formulary topical steroid. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FORM ALT PA VALSARTAN SOL

## Products Affected

- Valsartan SOLN

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) The patient has experienced an intolerance, caused by an inactive ingredient, to one other formulary product such as valsartan tablets, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FORM ALT TETRACYCLINE

## Products Affected

- Tetracycline Hydrochlorid
- Tetracycline Hydrochloride TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an intolerable adverse event to tetracycline capsules caused by an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FORM ALTERNATIVE PA

## Products Affected

- Glimepiride TABS 3MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an intolerance to one other formulary product. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FORTEO

## Products Affected

- Forteo INJ 600MCG/2.4ML
- Teriparatide

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For postmenopausal osteoporosis: patient has ONE of the following: 1) history of fragility fracture, OR 2) pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment Fracture Risk Assessment Tool (FRAX) fracture probability AND patient has ANY of the following: a) indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR b) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy OR c) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For primary or hypogonadal osteoporosis in men: patient has ONE of the following: 1) history of osteoporotic vertebral or hip fracture, OR 2) pre-treatment T-score of less than or equal to -2.5, or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability AND patient has ANY of the following: a) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy, OR b) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 24 months, Continuation: Plan Year |

| | |
|---|---|
| **Other Criteria** | For glucocorticoid-induced osteoporosis: Patient has had an oral bisphosphonate trial of at least 1-year duration unless patient has a contraindication or intolerance to an oral bisphosphonate, AND patient meets ANY of the following: 1) patient has a history of fragility fracture, OR 2) a pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability. Continuation of therapy: If the patient has received greater than or equal to 24 months of therapy with any parathyroid hormone analog: 1) The patient remains at or has returned to having a high risk for fracture, AND 2) The benefit of therapy with this prescribed medication outweighs the potential risks for this patient. |

# FOSCAVIR

## Products Affected

- Foscarnet Sodium INJ 6000MG/250ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | CMV Retinitis: 1) Patient has had an active lesion within the past 6 months OR 2) Patient has had a CD4 cell count less than 100/millimeters cubed (mm3) within the past 6 months. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CMV Retinitis: Prescribed by or in consultation with an ophthalmologist |
| **Coverage Duration** | CMV Retinitis: 6 months, Acyclovir-Resistant Mucocutaneous HSV infection: 1 month |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# FOTIVDA

## Products Affected

- Fotivda

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For advanced renal cell carcinoma: the following criteria must be met: 1) The disease is relapsed or refractory, 2) The requested drug must be used after at least two prior systemic therapies, and 3) The patient has experienced disease progression or an intolerable adverse event with a trial of Cabometyx (cabozantinib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FRUZAQLA

## Products Affected

- Fruzaqla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FYARRO

## Products Affected

- Fyarro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# FYCOMPA

## Products Affected

- Fycompa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam. For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Spritam. |
| **Age Restrictions** | Partial-onset seizures (i.e., focal-onset seizures): 4 years of age or older. Primary generalized tonic-clonic seizures: 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GALAFOLD

## Products Affected

- Galafold

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GATTEX

## Products Affected

- Gattex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For short bowel syndrome (SBS) initial therapy: 1) If the request is for an adult patient, the patient has been dependent on parenteral support for at least 12 months OR 2) If the request is for a pediatric patient, the patient is dependent on parenteral support. For SBS continuation: Requirement for parenteral support has decreased from baseline while on therapy with the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, gastrointestinal surgeon, or nutritional support specialist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GAVRETO

## Products Affected

- Gavreto

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent rearranged during transfection (RET) rearrangement-positive non-small cell lung cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For non-small cell lung cancer, patient must meet all of the following: 1) The disease is recurrent, advanced, or metastatic, and 2) The tumor is rearranged during transfection (RET) fusion-positive or RET rearrangement-positive. |
| **Age Restrictions** | Non-small cell lung cancer: 18 years of age or older. Medullary thyroid cancer and thyroid cancer: 12 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GAZYVA

**Products Affected**

- Gazyva

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Small lymphocytic lymphoma (SLL), gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, splenic marginal zone lymphoma, histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma, mantle cell lymphoma, diffuse large B-cell lymphoma, high-grade B-cell lymphomas, Burkitt lymphoma, acquired immune deficiency syndrome (AIDS)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, Castleman disease. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all diagnoses: the disease is CD20-positive. For gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma: the requested drug is used in any of the following settings: 1) second-line or subsequent therapy, or 2) maintenance therapy, or 3) a substitute for rituximab in a patient who has experienced an intolerance or rare complication (e.g., mucocutaneous reaction) to rituximab, or 4) first-line therapy (nodal marginal zone lymphoma indication only). For histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma, mantle cell lymphoma, diffuse large B-cell lymphoma, high-grade B-cell lymphomas, Burkitt lymphoma, acquired immune deficiency syndrome (AIDS)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, and Castleman disease: the patient has experienced an intolerance or rare complication (e.g., mucocutaneous reaction) to rituximab. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GILENYA

## Products Affected

- Fingolimod Hydrochloride
- Gilenya

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GILOTRIF

## Products Affected

- Gilotrif

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For non-small cell lung cancer (NSCLC): Patient meets either of the following: 1) Patient has metastatic squamous NSCLC that progressed after platinum-based chemotherapy, OR 2) Patient has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GIMOTI

## Products Affected

- Gimoti

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient will not use the requested drug for more than 12 consecutive weeks of therapy AND The patient has experienced an inadequate treatment response or intolerance to oral metoclopramide OR The patient is unable to take oral metoclopramide. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GIVLAARI

## Products Affected

- Givlaari

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GLATIRAMER

## Products Affected

- Copaxone INJ 20MG/ML, 40MG/ML
- Glatiramer Acetate
- Glatopa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GLOPERBA

## Products Affected

- Gloperba

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Pericarditis with multiple recurrences, Behcet's syndrome |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) The patient has experienced an inadequate treatment response or intolerance to Mitigare or generic colchicine tablets or capsules that was not attributed to the active ingredient, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GONADOTROPIN

## Products Affected

- Chorionic Gonadotropin INJ
- Novarel
- Pregnyl W/diluent Benzyl Alcohol/nacl

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Induction of ovulation |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GOPRELTO-NUMBRINO

## Products Affected

- Cocaine Hydrochloride
- Goprelto
- Numbrino

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# GRANIX

## Products Affected

- Granix

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Stem cell transplantation related indications, following chemotherapy for acute myeloid leukemia (AML), severe chronic neutropenia (congenital, cyclic, or idiopathic), neutropenia in myelodysplastic syndrome (MDS), agranulocytosis, neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia, hematopoietic syndrome of acute radiation syndrome |
| **Exclusion Criteria** | Use of the requested product within 24 hours prior to or following chemotherapy. |
| **Required Medical Information** | For prophylaxis or treatment of myelosuppressive chemotherapy-induced febrile neutropenia, patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, and 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# GRASTEK

## Products Affected

- Grastek

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy. History of eosinophilic esophagitis. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 5 to 65 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist or immunologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# GROWTH HORMONE

## Products Affected

- Genotropin
- Genotropin Miniquick

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **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 (TS): 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, nephrologist, infectious disease specialist, gastroenterologist/nutritional support specialist, or geneticist. |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | 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/m2 and high pretest probability of GHD [e.g., acquired structural abnormalities] or BMI less than 25 kg/m2, or d) GST [peak GH level less than or equal to 1 ng/ml] in pt with BMI 25-30 kg/m2 and low pretest probability of GHD or BMI greater than 30 kg/m2), 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. |

# HAEGARDA

## Products Affected

- Haegarda

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the prevention of acute angioedema attacks due to hereditary angioedema (HAE): The patient meets either of the following: 1) the patient has hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has hereditary angioedema with normal C1 inhibitor confirmed by laboratory testing and either of the following: a) 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 b) 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. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# HALAVEN

## Products Affected

- Eribulin Mesylate
- Halaven

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Soft tissue sarcoma (retroperitoneal/intra-abdominal soft tissue sarcoma, pleomorphic rhabdomyosarcoma, extremity/body wall, head/neck), recurrent breast cancer. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# HALOG SOLUTION AET

## Products Affected

- Halog SOLN

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses: the patient has experienced an inadequate treatment response or intolerance to a generic topical corticosteroid. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 Months |
| **Other Criteria** | N/A |

# HARVONI

## Products Affected

- Harvoni

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Criteria applied consistent w/ current AASLD-IDSA guidance. Reminder for 8wk option if appropriate. |
| **Other Criteria** | N/A |

# HERCEPTIN

## Products Affected

- Herceptin INJ 150MG
- Herzuma
- Kanjinti
- Ogivri
- Ontruzant

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma), HER2-positive recurrent salivary gland tumor, HER2-positive unresectable or metastatic hepatobiliary carcinoma (gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma), HER2 overexpression positive locally advanced, unresectable, or recurrent gastric adenocarcinoma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | All indications: the patient had an intolerable adverse event to Trazimera and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. For colorectal cancer (including appendiceal adenocarcinoma): 1) the disease is HER2-amplified and RAS and BRAF wild-type and 2) the requested drug is used in combination with pertuzumab, tucatinib or lapatinib and 3) the patient has not had previous treatment with a HER2 inhibitor. For hepatobiliary carcinoma: 1) the disease is HER2-positive AND 2) the requested drug is used in combination with pertuzumab. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# HERCEPTIN HYLECTA

## Products Affected

- Herceptin Hylecta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# HETLIOZ

## Products Affected

- Hetlioz
- Tasimelteon

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Non-24-Hour Sleep-Wake Disorder: 1) For initial therapy and continuation of therapy the patient must meet both of the following: a) diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas) and b) unable to perceive light in either eye, AND 2) If currently on therapy with the requested drug, patient must meet at least one of the following: a) increased total nighttime sleep or b) decreased daytime nap duration. For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): 1) For initial therapy and continuation therapy, the patient has a confirmed diagnosis of SMS AND 2) If currently on therapy with the requested drug, the patient experienced improvement in the quality of sleep since starting therapy. |
| **Age Restrictions** | Non-24: 18 years of age or older. SMS: 16 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a sleep disorder specialist, neurologist, or psychiatrist. |
| **Coverage Duration** | Initiation: 6 Months, Renewal: Plan Year |
| **Other Criteria** | N/A |

# HETLIOZ LQ

## Products Affected

- Hetlioz Lq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): 1) For initial therapy and continuation therapy, the patient has a confirmed diagnosis of SMS AND 2) If currently on therapy with the requested drug, the patient experienced improvement in the quality of sleep since starting therapy. |
| **Age Restrictions** | 3 to 15 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with a sleep disorder specialist or neurologist |
| **Coverage Duration** | Initiation: 6 Months, Renewal: Plan Year. |
| **Other Criteria** | N/A |

# HIGH RISK MEDICATION - 65

## Products Affected

- Anaspaz
- Atropine Sulfate INJ 0.25MG/5ML, 0.4MG/ML, 0.5MG/5ML, 1MG/10ML, 1MG/ML, 8MG/20ML
- Belladonna/opium
- Bentyl INJ
- Chlordiazepoxide/amitriptyline
- Demerol INJ 100MG/ML, 25MG/ML, 50MG/ML, 75MG/ML
- Dicyclomine Hcl SOLN
- Dicyclomine Hydrochloride CAPS
- Dicyclomine Hydrochloride INJ
- Dicyclomine Hydrochloride TABS
- Dihydroergotamine Mesylate INJ
- Diphenhydramine Hcl ELIX
- Dipyridamole TABS
- Disopyramide Phosphate CAPS
- Ergoloid Mesylates TABS
- Guanfacine Hydrochloride
- Guanfacine Hydrochloride Er
- Hyoscyamine Sulfate ELIX
- Hyoscyamine Sulfate SOLN
- Hyoscyamine Sulfate SUBL
- Hyoscyamine Sulfate TABS
- Hyoscyamine Sulfate Odt
- Indocin SUPP
- Indocin SUSP
- Indomethacin CAPS 25MG, 50MG
- Indomethacin SUPP 50MG
- Indomethacin SUSP
- Indomethacin Er
- Intuniv
- Ketorolac Tromethamine TABS
- Levsin TABS
- Levsin/sl
- Meperidine Hcl INJ 100MG/ML, 25MG/ML, 50MG/ML
- Meperidine Hcl ORAL SOLN
- Meperidine Hcl TABS 50MG
- Meprobamate
- Methscopolamine Bromide TABS
- Nifedipine CAPS
- Norpace
- Nulev
- Oscimin SUBL
- Oscimin TABS
- Pentazocine/naloxone Hcl
- Perphenazine/amitriptyline
- Promethazine Vc
- Ryclora
- Thioridazine Hcl TABS 100MG, 10MG, 25MG, 50MG
- Tigan INJ
- Trimethobenzamide Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. |

| | |
|---|---|
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HIZENTRA

## Products Affected

- Hizentra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# HRM - ANTICONVULSANTS - 65

## Products Affected

- Phenobarbital ELIX 20MG/5ML
- Phenobarbital TABS 100MG, 15MG, 16.2MG, 30MG, 32.4MG, 60MG, 64.8MG, 97.2MG
- Phenobarbital Sodium INJ 130MG/ML, 65MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Epilepsy |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRM - HYPNOTICS - 65

## Products Affected

- Ambien
- Ambien Cr
- Edluar
- Eszopiclone
- Lunesta
- Zaleplon
- Zolpidem Tartrate SUBL
- Zolpidem Tartrate TABS
- Zolpidem Tartrate Er
- Zolpimist

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For insomnia: 1) The patient meets one of the following: a) the patient has a contraindication to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) OR b) The non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND the patient experienced an inadequate treatment response OR intolerance to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 2) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient AND 3) If the patient is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, quetiapine, sertraline, clonazepam, escitalopram, alprazolam) with the requested drug, the prescriber has determined that taking multiple central nervous system (CNS) active medications is medically necessary for the patient [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls.]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) Prior authorization applies to greater than cumulative 90 days of therapy per year. |

# HRM - SCOPOLAMINE - 65

## Products Affected

- Scopolamine PT72 1MG/3DAYS
- Transderm-scop PT72 1MG/3DAYS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Excessive salivation |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRM-ANTIPARKINSON - 65

## Products Affected

- Benztropine Mesylate TABS
- Trihexyphenidyl Hcl SOLN
- Trihexyphenidyl Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. EPS (extrapyramidal symptoms): 1) The patient has not tried the non-HRM alternative drug amantadine AND 2) The patient has a contraindication to the non-HRM alternative drug amantadine OR 3) The patient has tried the non-HRM alternative drug amantadine AND 4) The patient experienced an inadequate treatment response OR intolerance to the non-HRM alternative drug amantadine. Parkinson's: 1) The patient has tried two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRM-CYPROHEPTADINE - 65

## Products Affected

- Cyproheptadine Hcl SYRP
- Cyproheptadine Hydrochloride TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Pruritus, spasticity due to spinal cord injury |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRM-DOXEPIN - 65

## Products Affected

- Doxepin Hcl CAPS 75MG
- Doxepin Hcl CONC
- Doxepin Hydrochloride CAPS 100MG, 10MG, 150MG, 25MG, 50MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone. For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRM-HYDROXYZINE - 65

## Products Affected

- Hydroxyzine Hcl TABS 50MG
- Hydroxyzine Hydrochloride SYRP
- Hydroxyzine Hydrochloride TABS 10MG, 25MG
- Hydroxyzine Pamoate CAPS
- Vistaril CAPS 25MG, 50MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety. For all indications: 1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. AND 2) If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, cyclobenzaprine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRM-HYDROXYZINE INJ - 65

## Products Affected

- Hydroxyzine Hcl INJ 25MG/ML
- Hydroxyzine Hydrochloride INJ

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For Alcohol Withdrawal Syndrome: 1) The patient has not tried one of the following alternative drugs: clorazepate or lorazepam AND 2) The patient has a contraindication to one of the following alternative drugs: clorazepate or lorazepam OR 3) The patient has tried one of the following alternative drugs: clorazepate or lorazepam AND 4) The patient experienced an inadequate treatment response OR intolerance to one of the following alternative drugs: clorazepate or lorazepam. For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRM-PROMETHAZINE - 65

## Products Affected

- Phenergan INJ
- Promethazine Hcl INJ
- Promethazine Hcl SUPP 12.5MG, 25MG
- Promethazine Hcl TABS 12.5MG
- Promethazine Hydrochloride TABS 25MG, 50MG
- Promethazine Hydrochloride Plain
- Promethegan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRMS - ANTIDEPRESSANTS

## Products Affected

- Amitriptyline Hcl TABS 100MG, 150MG, 25MG, 75MG
- Amitriptyline Hydrochloride TABS 100MG, 10MG, 50MG
- Desipramine Hydrochloride
- Imipramine Hcl TABS 25MG, 50MG
- Imipramine Hydrochloride TABS 10MG
- Imipramine Pamoate
- Norpramin TABS 10MG, 25MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Neuropathic pain |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRMS - CARBINOXAMINE

## Products Affected

- Carbinoxamine Maleate SOLN
- Carbinoxamine Maleate TABS
- Ryvent

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRMS - CLEMASTINE- 65

## Products Affected

- Clemastine Fumarate SYRP
- Clemastine Fumarate TABS 2.68MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRMS - DIABETES AGENTS

## Products Affected

- Glyburide TABS 1.25MG, 2.5MG, 5MG
- Glyburide Micronized
- Glyburide/metformin Hydrochloride
- Glynase TABS 1.5MG, 6MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) The patient has not tried one of the following non-HRM alternative drugs: glipizide or metformin AND 2) The patient has a contraindication to one of the following non-HRM alternative drugs: glipizide or metformin AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient OR 4) The patient has tried one of the following non-HRM alternative drugs: glipizide or metformin AND 5) The patient experienced an inadequate treatment response OR intolerance to one of the following non-HRM alternative drugs: glipizide or metformin AND 6) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRMS - TCAS

## Products Affected

- Protriptyline Hcl
- Trimipramine Maleate CAPS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **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.) |

# HRM-SKELETAL MUSCLE RELAXANTS - 65

## Products Affected

- Amrix
- Carisoprodol TABS
- Chlorzoxazone TABS
- Cyclobenzaprine Hydrochloride TABS
- Cyclobenzaprine Hydrochloride Er
- Fexmid
- Lorzone
- Metaxalone
- Methocarbamol INJ 1000MG/10ML
- Methocarbamol TABS
- Norgesic
- Norgesic Forte
- Orphenadrine Citrate INJ
- Orphenadrine Citrate Er
- Orphenadrine/aspirin/caffeine
- Orphengesic Forte
- Robaxin INJ 1000MG/10ML
- Soma
- Tanlor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient AND 2) If the patient is using one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, hydroxyzine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |

| | |
|---|---|
| **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.) Prior authorization applies to greater than cumulative 90 days of therapy per year. |

# HUMIRA

## Products Affected

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pen
- Humira Pen-cd/uc/hs Starter INJ 80MG/0.8ML
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | For non-infectious intermediate, posterior and panuveitis (new starts only): 1) patient has experienced an inadequate treatment response or intolerance to a corticosteroid OR 2) the patient has a contraindication that would prohibit a trial of corticosteroids. |

# HYFTOR

## Products Affected

- Hyftor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# HYPERINFLATION NEURO-PSYCH-PAIN

## Products Affected

- Diclofenac Potassium CAPS
- Diclofenac Potassium TABS 25MG
- Lofena
- Tramadol Hydrochloride TABS 25MG
- Zipsor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an intolerance to one other formulary product. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# HYPNOTIC-BENZODIAZEPINES - 65

## Products Affected

- Estazolam
- Halcion TABS 0.25MG
- Restoril CAPS 15MG, 22.5MG, 7.5MG
- Temazepam CAPS 15MG, 22.5MG, 7.5MG
- Triazolam

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For short-term treatment of insomnia: 1) Prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: 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.) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | This Prior Authorization only applies to patients 65 years of age or older. Prior authorization applies to greater than cumulative 90 days of therapy per year. |

# HYQVIA

## Products Affected

- Hyqvia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# IBRANCE

## Products Affected

- Ibrance

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Unresectable well-differentiated/dedifferentiated liposarcoma of the retroperitoneum, recurrent hormone receptor-positive human epidermal growth factor receptor 2 (HER2)-negative breast cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IBSRELA AET

## Products Affected

- Ibsrela

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For irritable bowel syndrome with constipation (IBS-C): The patient has had an inadequate treatment response, intolerance, or has a contraindication to Linzess (linaclotide). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ICATIBANT

## Products Affected

- Firazyr
- Icatibant Acetate
- Sajazir

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute angioedema attacks due to hereditary angioedema (HAE): Patient meets either of the following: 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the 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 b) the 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. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ICLUSIG

**Products Affected**

- Iclusig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Myeloid and/or lymphoid neoplasms with eosinophilia and FGFR1 or ABL1 rearrangement in the chronic phase or blast phase |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: 1) patient has accelerated or blast phase CML and no other kinase inhibitor is indicated OR 2) patient has chronic phase CML and has experienced resistance or intolerance to at least 2 prior kinase inhibitors AND at least one of those was imatinib or dasatinib OR 3) patient is positive for the T315I mutation. For acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IDACIO

## Products Affected

- Adalimumab-aacf (2 Pen)
- Adalimumab-aacf (2 Syringe)
- Idacio (2 Pen)
- Idacio (2 Syringe)
- Idacio Starter Package For Crohns Disease
- Idacio Starter Package For Plaque Psoriasis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | For non-infectious intermediate, posterior and panuveitis (new starts only): 1) patient has experienced an inadequate treatment response or intolerance to a corticosteroid OR 2) the patient has a contraindication that would prohibit a trial of corticosteroids. |

# IDHIFA

## Products Affected

- Idhifa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Newly-diagnosed acute myeloid leukemia |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation: 1) patient is 60 years of age or older with newly-diagnosed AML and meets one of the following: a) patient is not a candidate for intensive induction therapy, or b) patient declines intensive induction chemotherapy, OR 2) patient is 60 years of age or older and the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug, OR 3) patient has relapsed or refractory AML. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IGALMI

## Products Affected

- Igalmi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# ILARIS

## Products Affected

- Ilaris INJ 150MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For active systemic juvenile idiopathic arthritis or active adult-onset Still's disease (new starts only), patient must meet either of the following criteria: 1) inadequate response to a nonsteroidal anti-inflammatory drug (NSAID), a corticosteroid, methotrexate, or leflunomide, OR 2) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD). For gout flares, patient must meet all of the following (new starts): 1) two or more gout flares within the previous 12 months prior to the initial treatment with the requested drug, AND 2) inadequate response, intolerance, or contraindication to at least two of the following: non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, or corticosteroids. For gout flares (continuation): patient experienced a positive clinical response from treatment with the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ILUMYA

## Products Affected

- Ilumya

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IMATINIB

## Products Affected

- Gleevec TABS
- Imatinib Mesylate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Desmoid tumors, pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT), recurrent chordoma, melanoma, Kaposi sarcoma, chronic graft versus host disease (cGVHD), T-cell acute lymphoblastic leukemia with ABL-class translocation, aggressive systemic mastocytosis for well-differentiated systemic mastocytosis (WDSM) or when eosinophilia is present with FIP1L1-PDGFRA fusion gene, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1, FIP1L1-PDGFRA, or PDGFRB rearrangement in the chronic phase or blast phase |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), including patients who have received a hematopoietic stem cell transplant: diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML: patient did not fail (excluding failure due to intolerance) prior therapy with a tyrosine kinase inhibitor. For melanoma: c-Kit mutation is positive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IMBRUVICA

## Products Affected

- Imbruvica

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Hairy cell leukemia, lymphoplasmacytic lymphoma, primary central nervous system (CNS) lymphoma, Human Immunodeficiency Virus (HIV) -related B-cell lymphoma, diffuse large B-cell lymphoma, post-transplant lymphoproliferative disorders, high-grade B-cell lymphoma, mantle cell lymphoma, marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, splenic marginal zone lymphoma) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For mantle cell lymphoma: 1) the requested drug will be used as second-line or subsequent therapy, OR 2) the requested drug will be used in combination with rituximab as pretreatment to induction therapy with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen, OR 3) the requested drug will be used as aggressive induction therapy. For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug will be used as second-line or subsequent therapy. For hairy cell leukemia: the requested drug will be used as a single agent for disease progression. For primary CNS lymphoma: 1) the disease is relapsed or refractory, OR 2) the requested drug is used for induction therapy as a single agent. For diffuse large B-cell lymphoma and high-grade B-cell lymphoma: the requested drug will be used as second-line or subsequent therapy. For HIV-related B-cell lymphoma: the requested drug will be used as a single agent and as second-line or subsequent therapy for relapsed disease. For post-transplant lymphoproliferative disorders: the requested drug will be used in patients who have received prior chemoimmunotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IMDELLTRA

## Products Affected

- Imdelltra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IMFINZI

**Products Affected**

- Imfinzi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Unresectable stage II non-small cell lung cancer, metastatic hepatocellular carcinoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For unresectable Stage II and III non-small cell lung cancer: The disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. For biliary tract cancers: Patient has locally advanced, unresectable, recurrent, or metastatic disease. For hepatocellular carcinoma: Patient has unresectable or metastatic disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IMJUDO

## Products Affected

- Imjudo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IMLYGIC

## Products Affected

- Imlygic

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For melanoma: The requested drug will be used for the treatment of cutaneous, subcutaneous, or nodal lesions. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IMPAVIDO

## Products Affected

- Impavido

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Pregnancy. Sjogren-Larsson-Syndrome. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 28 days |
| **Other Criteria** | N/A |

# IMVEXXY

## Products Affected

- Imvexxy Maintenance Pack
- Imvexxy Starter Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# INBRIJA

## Products Affected

- Inbrija

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For initial treatment of "off" episodes in Parkinson's disease: 1) The patient is currently being treated with oral carbidopa/levodopa, 2) The patient does not have any of the following: asthma, chronic obstructive pulmonary disease (COPD), or other chronic underlying lung disease. For continuation treatment of "off" episodes in Parkinson's disease: The patient is experiencing improvement on the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# INCRELEX

## Products Affected

- Increlex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Pediatric patients with closed epiphyses |
| **Required Medical Information** | 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. |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# INFLECTRA

## Products Affected

- Inflectra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Behcet's syndrome, hidradenitis suppurativa, juvenile idiopathic arthritis, pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, uveitis. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) Pt meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) or leflunomide OR b) intolerance or CI to MTX AND leflunomide, AND 2) Pt meets ANY of the following: a) inadequate response, intolerance or CI to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at time of diagnosis, AND 2) Pt meets ANY of the following: a) pt has experienced inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with MTX, cyclosporine, or acitretin, OR b) pharmacologic treatment with MTX, cyclosporine, or acitretin is contraindicated, OR c) pt has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | For hidradenitis suppurativa (new starts only): Pt has severe, refractory disease. For uveitis (new starts only): Inadequate response or intolerance or has a CI to a trial of immunosuppressive therapy for uveitis. For FDA-approved indications and off-label uses that overlap: The patient had an intolerable adverse event to Renflexis and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. |

# INGREZZA

## Products Affected

- Ingrezza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# INLYTA

## Products Affected

- Inlyta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Thyroid carcinoma (papillary, Hurthle cell, or follicular), alveolar soft part sarcoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For renal cell carcinoma: The disease is advanced, relapsed, or stage IV. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# INPEFA

## Products Affected

- Inpefa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# INQOVI

## Products Affected

- Inqovi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# INREBIC

## Products Affected

- Inrebic

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and janus kinase 2 (JAK2) rearrangement, accelerated phase myelofibrosis, blast phase myelofibrosis/acute myeloid leukemia |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# INTRAROSA

## Products Affected

- Intrarosa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IQIRVO

**Products Affected**

- Iqirvo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary biliary cholangitis (PBC): For initial therapy: 1) Diagnosis of PBC is confirmed by at least two of the following: a) Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration, b) Presence of antimitochondrial antibodies (AMA) (titer greater than 1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies ANA (e.g., anti-gp210, anti-sp100), c) Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts), AND 2) Patient has an elevated serum ALP level prior to initiation of therapy with the requested drug and meets one of the following requirements: a) Has experienced an inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol and the patient will continue concomitant therapy with UDCA/ursodiol, b) Is intolerant to prior therapy with UDCA/ursodiol. For PBC (continuation): Patient achieved or maintained a clinical benefit from Iqirvo therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# IR BEFORE ER

## Products Affected

- Hydrocodone Bitartrate Er
- Hydromorphone Hcl Er TB24 12MG, 16MG, 8MG
- Hydromorphone Hydrochloride Er TB24 32MG
- Hysingla Er
- Methadone Hcl INJ
- Methadone Hcl ORAL SOLN
- Methadone Hcl TABS
- Methadone Hydrochloride CONC
- Methadose CONC 10MG/ML
- Methadose Sugar-free
- Morphine Sulfate Er TBCR 100MG, 200MG
- Ms Contin TBCR 100MG, 200MG
- Oxymorphone Hydrochloride Er TB12 10MG, 15MG, 20MG, 30MG, 5MG, 7.5MG
- Oxymorphone Hydrochlorideer
- Xtampza Er

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe enough to require daily, around-the-clock, long-term treatment in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | N/A |

# IRESSA

## Products Affected

- Gefitinib
- Iressa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent non-small cell lung cancer (NSCLC). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For NSCLC: 1) disease must be metastatic, advanced, or recurrent and 2) patient must have a sensitizing EGFR mutation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ISOTRETINOIN

## Products Affected

- Absorica
- Accutane
- Amnesteem
- Claravis
- Isotretinoin CAPS
- Zenatane

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Refractory acne vulgaris, severe refractory rosacea, neuroblastoma, cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides, Sezary syndrome), high risk for developing skin cancer (squamous cell cancers), transient acantholytic dermatosis (Grover's Disease), keratosis follicularis (Darier Disease), lamellar ichthyosis, pityriasis rubra pilaris. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ISTURISA

## Products Affected

- Isturisa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ITRACONAZOLE

## Products Affected

- Itraconazole CAPS
- Itraconazole SOLN
- Sporanox CAPS
- Sporanox SOLN

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Coccidioidomycosis, Coccidioidomycosis prophylaxis in HIV infection,, Cryptococcosis, Microsporidiosis, Talaromycosis (formerly Penicilliosis), Histoplasmosis prophylaxis in HIV infection, Invasive fungal infection prophylaxis in liver transplant, chronic granulomatous disease (CGD), and hematologic malignancy, Sporotrichosis, Pityriasis versicolor, Tinea versicolor, Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis, primary treatment for allergic bronchopulmonary aspergillosis, primary treatment for chronic cavitary or subacute invasive (necrotizing) pulmonary aspergillosis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 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). For primary treatment of allergic bronchopulmonary aspergillosis, the requested drug is initiated in combination with systemic corticosteroids. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Disseminated/CNS histo, histo/CM/CGD ppx, chronic cavitary/necrotizing PA: 12 mths. Others: 6 mths |
| **Other Criteria** | N/A |

# IVERMECTIN TAB

## Products Affected

- Ivermectin TABS
- Stromectol TABS 3MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Ascariasis, Cutaneous larva migrans, Mansonelliasis, Scabies, Gnathostomiasis, Pediculosis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug is not being prescribed for the prevention or treatment of coronavirus disease 2019 (COVID-19). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# IVIG

## Products Affected

- Alyglo
- Asceniv
- Bivigam INJ 10%, 5GM/50ML
- Flebogamma Dif
- Gammagard Liquid
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked INJ 10GM/100ML, 1GM/10ML, 20GM/200ML, 5GM/50ML
- Gammaplex INJ 10GM/100ML, 10GM/200ML, 20GM/200ML, 20GM/400ML, 5GM/100ML, 5GM/50ML
- Gamunex-c
- Octagam INJ 10GM/100ML, 10GM/200ML, 1GM/20ML, 2.5GM/50ML, 20GM/200ML, 2GM/20ML, 30GM/300ML, 5GM/100ML, 5GM/50ML
- Panzyga
- Privigen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For B-cell chronic lymphocytic leukemia (CLL): 1) serum IgG less than 500 mg/dL OR 2) a history of recurrent bacterial infections. For bone marrow transplant/hematopoietic stem cell transplant (BMT/HSCT): 1) IVIG is requested within the first 100 days post-transplant OR 2) serum IgG less than 400 mg/dL. For pediatric human immunodeficiency virus (HIV) infection: 1) serum IgG less than 400 mg/dL OR 2) history of recurrent bacterial infections. For dermatomyositis and polymyositis: 1) at least one standard first-line treatment (corticosteroid or immunosuppressant) has been tried but was unsuccessful or not tolerated OR 2) patient is unable to receive standard therapy because of a contraindication or other clinical reason. For pure red cell aplasia (PRCA): PRCA is secondary to parvovirus B19 infection. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# IWILFIN

**Products Affected**

- Iwilfin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IXEMPRA

## Products Affected

- Ixempra Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent breast cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# IZERVAY

## Products Affected

- Izervay

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For geographic atrophy (GA) secondary to age-related macular degeneration (AMD): Patient has not previously received 12 or more months of therapy with the requested drug in each affected eye. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# JAKAFI

## Products Affected

- Jakafi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Lower-risk myelofibrosis, accelerated phase myelofibrosis, blast phase myelofibrosis/acute myeloid leukemia, acute lymphoblastic leukemia (ALL), chronic myelomonocytic leukemia (CMML)-2, myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) with neutrophilia, essential thrombocythemia, and myeloid, lymphoid or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For polycythemia vera: patient had an inadequate response or intolerance to interferon therapy or hydroxyurea. For acute lymphoblastic leukemia: patient has a cytokine receptor-like factor 2 (CRLF2) mutation or a mutation associated with activation of the Janus kinase/signal transducers and activators of transcription (JAK/STAT) pathway. For CMML-2: the requested drug is used in combination with a hypomethylating agent. For myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) with neutrophilia: the requested drug is used as a single agent or in combination with a hypomethylating agent. For essential thrombocythemia: patient had an inadequate response or loss of response to hydroxyurea, interferon therapy, or anagrelide. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# JATENZO

## Products Affected

- Jatenzo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Gender Dysphoria |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# JAYPIRCA

## Products Affected

- Jaypirca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): The patient meets both of the following: 1) The patient has received prior treatment with one of the following: Imbruvica (ibrutinib), Brukinsa (zanubrutinib), or Calquence (acalabrutinib), AND 2) The patient has received prior treatment with a B-cell lymphoma 2 (BCL-2) inhibitor. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# JEMPERLI

## Products Affected

- Jemperli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For solid tumors: the patient has mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# JEVTANA

## Products Affected

- Jevtana

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient has a diagnosis of metastatic castration-resistant prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# JOENJA

## Products Affected

- Joenja

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For activated phosphoinositide 3-kinase delta syndrome (APDS): the diagnosis was confirmed by genetic testing demonstrating variant in either PIK3CD or PIK3R1. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# JUBLIA AET

## Products Affected

- Jublia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to an adequate trial of one systemic (oral) antifungal alternative such as terbinafine AND 2) Diagnosis of onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes has been confirmed by a positive fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture or nail biopsy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 48 weeks |
| **Other Criteria** | N/A |

# JUXTAPID

## Products Affected

- Juxtapid CAPS 10MG, 20MG, 30MG, 5MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For initiation of therapy to treat homozygous familial hypercholesterolemia (HoFH), patient (pt) must meet ALL of the following: A) Diagnosis of HoFH confirmed by one of the following: 1) Genetic testing to confirm two mutant alleles at low-density lipoprotein receptor (LDLR), apolipoprotein B (ApoB), proprotein convertase subtilisin/kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus OR 2) History of an untreated low-density lipoprotein-cholesterol (LDL-C) of greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL and either of the following: a) Presence of cutaneous or tendinous xanthomas before the age of 10 years, or b) An untreated LDL-C level of greater than or equal to 190 mg/dL in both parents, which is consistent with heterozygous familial hypercholesterolemia (HeFH), AND B) Prior to initiation of treatment, the pt is currently receiving treatment with a high-intensity statin at a maximally tolerated dose or at the maximum dose approved by the Food and Drug Administration (FDA) unless the pt is statin intolerant or has a contraindication to statin therapy, AND C) Prior to initiation of treatment with the requested drug, the pt is currently receiving treatment with a PCSK9-directed therapy at a maximally tolerated dose or at the maximum dose approved by the FDA unless the patient has experienced an intolerance or has a contraindication to all PCSK9-directed therapies, AND D) Prior to initiation of treatment, pt is/was experiencing an inadequate response to lipid-lowering therapy as indicated by a treated LDL-C greater than 100 mg/dL (or greater than 70 mg/dL with clinical atherosclerotic cardiovascular disease), AND E) The pt will continue to receive concomitant lipid lowering therapy. For renewal of therapy to treat HoFH: A) Pt meets all initial criteria, AND B) Has responded to therapy as demonstrated by a reduction in LDL-C from baseline, AND C) Is receiving concomitant lipid lowering therapy. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# JYNARQUE

## Products Affected

- Jynarque

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KALBITOR

## Products Affected

- Kalbitor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute angioedema attacks due to hereditary angioedema (HAE): Patient meets either of the following: 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the 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 b) the 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. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KALYDECO

## Products Affected

- Kalydeco

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KANUMA

## Products Affected

- Kanuma

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For lysosomal acid lipase deficiency: Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of lysosomal acid lipase enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KERYDIN AET

## Products Affected

- Tavaborole

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to an adequate trial of one systemic (oral) antifungal alternative such as terbinafine AND 2) Diagnosis of onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes has been confirmed by a positive fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture or nail biopsy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 48 weeks |
| **Other Criteria** | N/A |

# KESIMPTA

## Products Affected

- Kesimpta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KETOCONAZOLE

**Products Affected**

- Ketoconazole TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Cushing's syndrome |
| **Exclusion Criteria** | 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. |
| **Required Medical Information** | 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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# KEVEYIS

## Products Affected

- Dichlorphenamide
- Keveyis
- Ormalvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary HYPOkalemic periodic paralysis: 1) The diagnosis was supported by genetic test results, OR 2) Patient has a family history of primary hypokalemic periodic paralysis, OR 3) Patient's attacks are associated with hypokalemia AND both Andersen-Tawil syndrome and thyrotoxic periodic paralysis have been ruled out. For primary HYPERkalemic periodic paralysis: 1) The diagnosis was supported by genetic test results, OR 2) Patient has a family history of primary hyperkalemic periodic paralysis, OR 3) Patient's attacks are associated with hyperkalemia AND Andersen-Tawil syndrome has been ruled out. For continuation of therapy for primary HYPOkalemic and primary HYPERkalemic periodic paralysis: Patient is demonstrating a response to therapy with the requested drug as demonstrated by a decrease in the number or severity of attacks. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 2 months. Continuation: 12 months |
| **Other Criteria** | N/A |

# KEVZARA

## Products Affected

- Kevzara

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has had an inadequate response, intolerance or contraindication to methotrexate (MTX) OR 2) patient has had an inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For polymyalgia rheumatica (PMR) (new starts only): 1) The patient has experienced an inadequate treatment response to corticosteroids OR 2) The patient has experienced a disease flare while attempting to taper corticosteroids. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KEYTRUDA

## Products Affected

- Keytruda INJ 100MG/4ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KIMMTRAK

## Products Affected

- Kimmtrak

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KINERET

## Products Affected

- Kineret

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Systemic juvenile idiopathic arthritis, adult-onset Still's disease, multicentric Castleman's disease, Schnitzler syndrome, and Erdheim-Chester disease. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib-extended release). For active systemic juvenile idiopathic arthritis (new starts only): patient must meet any of the following criteria: 1) Inadequate response to at least one nonsteroidal anti-inflammatory drug (NSAID), corticosteroid, methotrexate or leflunomide, 2) Inadequate response or intolerance to a prior biologic DMARD, OR 3) Physician global assessment score greater than or equal to 5. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KISQALI

## Products Affected

- Kisqali
- Kisqali Femara 200 Dose
- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer, in combination with an aromatase inhibitor, or fulvestrant. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KLISYRI

## Products Affected

- Klisyri

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following: A) imiquimod 5 percent cream, B) fluorouracil cream or solution. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KONVOMEP

## Products Affected

- Konvomep

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of active benign gastric ulcer: 1) The patient has experienced an inadequate treatment response to a one-month trial each of two proton pump inhibitors (PPIs), OR 2) The patient has experienced an intolerance, or the patient has a contraindication that would prohibit a one-month trial of two proton pump inhibitors (PPIs), AND 3) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# KORLYM

## Products Affected

- Korlym
- Mifepristone TABS 300MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KOSELUGO

## Products Affected

- Koselugo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | BRAF fusion or BRAF V600E activating mutation-positive recurrent or progressive pilocytic astrocytoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | For neurofibromatosis type 1: 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KRAZATI

## Products Affected

- Krazati

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KRINTAFEL

## Products Affected

- Krintafel

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Glucose-6-phosphate dehydrogenase (G6PD) deficiency or unknown G6PD status. |
| **Required Medical Information** | The patient is receiving chloroquine-based therapy for acute Plasmodium vivax infection. |
| **Age Restrictions** | 16 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# KRISTALOSE

## Products Affected

- Kristalose
- Lactulose PACK

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For constipation: 1) The patient has experienced an inadequate treatment response to a one month trial of generic lactulose solution, OR 2) The patient has experienced an intolerance that would prohibit a one month trial of generic lactulose solution, OR 3) the patient has a contraindication to an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KRYSTEXXA

## Products Affected

- Krystexxa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will not be used concomitantly with oral urate-lowering agents. For initiation of therapy for chronic gout: 1) the patient must meet either of the following: a) patient has had an inadequate response to a 3-month trial of a xanthine oxidase inhibitor at the maximum medically appropriate dose unless there is a clinical reason for not completing a trial (e.g., severe allergic reaction, toxicity, intolerance, significant drug interaction, severe renal dysfunction [for allopurinol only], end stage renal impairment [for febuxostat only], or history of CVD or a new CV event [for febuxostat only]), or b) if there is a clinical reason for not completing a 3-month trial with a xanthine oxidase inhibitor, an inadequate response to a 3-month trial of probenecid is required unless there is a clinical reason for not completing a trial of probenecid (e.g., renal insufficiency [glomerular filtration rate of 30 mL per minute or less], severe allergic reaction, toxicity, intolerance, existing blood dyscrasias or uric acid kidney stones, and significant drug interaction) AND 2) the patient experiences frequent gout flares (greater than or equal to 2 per year) OR the patient has at least 1 gout tophus or gouty arthritis. For continuation of therapy for treatment of chronic gout: 1) patient has not had 2 consecutive uric acid levels above 6 mg/dL, AND 2) patient is experiencing benefit from therapy (e.g., serum uric acid levels less than 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# KYPROLIS

## Products Affected

- Kyprolis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Waldenstrom macroglobulinemia, lymphoplasmacytic lymphoma, relapsed/refractory systemic light chain amyloidosis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LAGEVRIO AET

## Products Affected

- Lagevrio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in a non-hospitalized patient ALL of the following are met: 1) patient is at high risk for progression to severe COVID-19 (e.g., age 60 or older, body mass index [BMI] 30 or greater, hypertension, diabetes mellitus, chronic lung disease), including hospitalization and death, AND 2) treatment with the requested drug is initiated within 5 days of symptom onset. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 30 days |
| **Other Criteria** | N/A |

# LAMPIT

## Products Affected

- Lampit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient has serologic evidence of Trypanosoma cruzi infection. |
| **Age Restrictions** | Less than 18 years of age |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 2 months |
| **Other Criteria** | N/A |

# LAMZEDE

## Products Affected

- Lamzede

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For non-central nervous system manifestations of alpha-mannosidosis: Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of alpha-mannosidase enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LAPATINIB

## Products Affected

- Lapatinib Ditosylate
- Tykerb

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Brain metastases from human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent HER2-positive breast cancer, recurrent epidermal growth factor receptor (EGFR)-positive chordoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For breast cancer, the patient meets all the following: a) the disease is recurrent, advanced, or metastatic (including brain metastases), b) the disease is human epidermal growth factor receptor 2 (HER2)-positive, c) the requested drug will be used in combination with any of the following: 1) aromatase inhibitor, 2) capecitabine, OR 3) trastuzumab. For colorectal cancer: 1) requested drug will be used in combination with trastuzumab and 2) patient has not had previous treatment with a HER2 inhibitor. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LAZCLUZE

## Products Affected

- Lazcluze

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LEDIPASVIR-SOFOSBUVIR AET

**Products Affected**

- Ledipasvir/sofosbuvir

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. The patient must have a contraindication or has experienced an intolerance to 2 of the following, if appropriate, based on current AASLD/IDSA guidance: Epclusa (velpatasvir and sofosbuvir), Harvoni (ledipasvir and sofosbuvir), Mavyret (glecaprevir and pibrentasvir), Vosevi (sofosbuvir, velpatasvir, and voxilaprevir) AND the criteria will be applied consistent with current AASLD/IDSA guidance. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Criteria applied consistent w/ current AASLD-IDSA guidance. Reminder for 8wk option if appropriate. |
| **Other Criteria** | N/A |

# LEMTRADA AET

## Products Affected

- Lemtrada

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including relapsing-remitting disease and active secondary progressive disease]: Patient must have tried and failed or has a contraindication or intolerance to two of the following: brand Aubagio, Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone, brand Tecfidera, Vumerity (diroximel fumarate), Zeposia (ozanimod). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LENVIMA

## Products Affected

- Lenvima 10 Mg Daily Dose
- Lenvima 12mg Daily Dose
- Lenvima 14 Mg Daily Dose
- Lenvima 18 Mg Daily Dose
- Lenvima 20 Mg Daily Dose
- Lenvima 24 Mg Daily Dose
- Lenvima 4 Mg Daily Dose
- Lenvima 8 Mg Daily Dose

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Medullary thyroid carcinoma, recurrent endometrial carcinoma, thymic carcinoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For differentiated thyroid cancer (follicular, papillary, or Hurthle cell): disease is not amenable to radioactive iodine therapy and unresectable, locally recurrent, persistent, or metastatic. For hepatocellular carcinoma: disease is unresectable or inoperable, local, metastatic or with extensive liver tumor burden. For renal cell carcinoma, the disease is advanced, relapsed, or stage IV. For endometrial carcinoma, the patient meets ALL of the following: 1) The disease is advanced, recurrent, or metastatic, 2) The requested drug will be used in combination with pembrolizumab, 3) The patient experienced disease progression following prior systemic therapy, AND 4) The patient is not a candidate for curative surgery or radiation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LEQVIO

## Products Affected

- Leqvio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LEUKINE

## Products Affected

- Leukine INJ 250MCG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Prophylaxis of chemotherapy-induced febrile neutropenia (FN), neutropenia in myelodysplastic syndromes (MDS), neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia, severe chronic neutropenia (congenital, cyclic, or idiopathic). |
| **Exclusion Criteria** | Use of the requested product within 24 hours prior to or following chemotherapy. |
| **Required Medical Information** | For prophylaxis of chemotherapy-induced febrile neutropenia (FN), the patient must meet both of the following: 1) Patient has a non-myeloid cancer, and 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# LEUPROLIDE

## Products Affected

- Leuprolide Acetate INJ 1MG/0.2ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Use in combination with growth hormone for children with growth failure and advancing puberty, recurrent androgen receptor positive salivary gland tumors, central precocious puberty. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For central precocious puberty (CPP): Patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, AND 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, AND 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients. |
| **Age Restrictions** | CPP: Patient must be less than 12 years old if female and less than 13 years old if male |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LIBERVANT

## Products Affected

- Libervant

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 2 to 5 years of age |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LIBRAX

## Products Affected

- Chlordiazepoxide Hydrochloride/clidinium Bromide
- Librax

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | If the patient is 65 years of age or older, the prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. (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.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LIBTAYO

## Products Affected

- Libtayo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent non-small cell lung cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cutaneous squamous cell carcinoma: the patient is not a candidate for curative surgery or curative radiation. For basal cell carcinoma: the patient was previously treated with a hedgehog pathway inhibitor OR treatment with a hedgehog pathway inhibitor is not appropriate. For non-small cell lung cancer (NSCLC): 1) the disease is advanced, recurrent, or metastatic AND 2) the tumor does not have an epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or proto-oncogene tyrosine-protein kinase ROS (ROS1) aberration. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LICART AET

## Products Affected

- Licart

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs). For treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery. |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two generic oral nonsteroidal anti-inflammatory drugs (NSAIDs). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# LIDOCAINE PATCHES

## Products Affected

- Lidocaine PTCH 5%
- Lidocan
- Lidoderm
- Lidotral 1
- Tridacaine
- Tridacaine II

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Pain associated with diabetic neuropathy, pain associated with cancer-related neuropathy (including treatment-related neuropathy [e.g., neuropathy associated with radiation treatment or chemotherapy]). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LIDOTRAL HC

## Products Affected

- Lidotral/hydrocortisone W/peptides & Arnica

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) The patient has experienced an intolerance to one of the following formulary products: lidocaine ointment 5%, hydrocortisone cream 1% OR 2) Use of the drug is associated with radiation treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LINEZOLID

## Products Affected

- Linezolid
- Zyvox

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. The patient will be using the requested drug orally or intravenously. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed or directed by an Infectious Disease specialist when being converted from intravenous (IV) linezolid (Zyvox) |
| **Coverage Duration** | 28 days |
| **Other Criteria** | N/A |

# LIQREV

## Products Affected

- Liqrev

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LITFULO

## Products Affected

- Litfulo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For severe alopecia areata (initial): 1) Patient has at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) AND 2) Patient does not have primarily diffuse pattern alopecia (characterized by diffuse hair shedding) or other forms of alopecia (e.g., androgenetic alopecia, trichotillomania, telogen effluvium, chemotherapy-induced hair loss). For severe alopecia areata (continuation): Patient has achieved or maintained a positive clinical response as evidenced by an improvement in signs and symptoms of the condition from baseline (e.g., increased scalp hair coverage). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LIVDELZI

**Products Affected**

- Livdelzi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary biliary cholangitis (PBC): For initial therapy: 1) Diagnosis of PBC is confirmed by at least two of the following: a) Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration, b) Presence of antimitochondrial antibodies (AMA) (titer greater than 1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies ANA (e.g., anti-gp210, anti-sp100), c) Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts), AND 2) Patient has an elevated serum ALP level prior to initiation of therapy with the requested drug and meets one of the following requirements: a) Has experienced an inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol and the patient will continue concomitant therapy with UDCA/ursodiol, b) Is intolerant to prior therapy with UDCA/ursodiol. For PBC (continuation): Patient achieved or maintained a clinical benefit from Livdelzi therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# LIVMARLI

## Products Affected

- Livmarli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of cholestatic pruritis in a patient with Alagille syndrome (ALGS) (continuation): the patient has experienced benefit from therapy (for example, improvement in pruritis). For treatment of cholestatic pruritis in a patient with Progressive Familial Intrahepatic Cholestasis (PFIC), (initial): 1) diagnosis of PFIC has been confirmed by genetic testing, AND 2) the patient does not have PFIC type 2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump (BSEP) protein, AND 3) the patient does not have any other concomitant liver disease, AND 4) the patient has not received a liver transplant. For treatment of cholestatic pruritis in a patient with PFIC, (continuation): the patient has experienced benefit from therapy (for example, improvement in pruritis). |
| **Age Restrictions** | For ALGS: 3 months of age or older, For PFIC: 12 months of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hepatologist or gastroenterologist |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# LIVTENCITY

## Products Affected

- Livtencity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist, transplant specialist, hematologist, or oncologist. |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# LODOCO

## Products Affected

- Lodoco

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LONSURF

## Products Affected

- Lonsurf

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For colorectal cancer (including appendiceal adenocarcinoma): The disease is advanced or metastatic. For gastric or gastroesophageal junction adenocarcinoma, all of the following criteria must be met: 1) The disease is unresectable locally advanced, recurrent, or metastatic, and 2) The patient has been previously treated with at least two prior lines of chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LOQTORZI

## Products Affected

- Loqtorzi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LORBRENA

## Products Affected

- Lorbrena

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Anaplastic lymphoma kinase (ALK)-positive recurrent non-small cell lung cancer (NSCLC). Repressor of silencing (ROS)-1 rearrangement-positive recurrent, advanced, or metastatic NSCLC following progression on crizotinib, entrectinib, or ceritinib. Symptomatic or relapsed/refractory ALK-positive Erdheim-Chester Disease. Inflammatory myofibroblastic tumor (IMT) with ALK translocation. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For recurrent, advanced, or metastatic NSCLC: Patient has ALK-positive disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LOREEV XR

## Products Affected

- Loreev Xr

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For anxiety disorder: 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 disorder, OR the patient 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), or b) serotonin-norepinephrine reuptake inhibitors (SNRIs) AND 2) The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient (Note: 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). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 4 months |
| **Other Criteria** | This Prior Authorization only applies to patients 65 years of age or older. |

# LUCEMYRA

## Products Affected

- Lofexidine Hydrochloride
- Lucemyra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# LUCENTIS

## Products Affected

- Lucentis SOSY

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# LUMAKRAS

## Products Affected

- Lumakras

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent KRAS G12C-positive non-small cell lung cancer (NSCLC) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LUMIZYME

**Products Affected**

- Lumizyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Pompe disease: Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of acid alpha-glucosidase (GAA) enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LUMRYZ

**Products Affected**

- Lumryz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of excessive daytime sleepiness in a patient with narcolepsy, initial request: 1) The diagnosis has been confirmed by sleep lab evaluation, AND 2) The patient experienced an inadequate treatment response or intolerance to at least one CNS wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of CNS wakefulness promoting drugs (e.g., armodafinil, modafinil). For the treatment of cataplexy in a patient with narcolepsy, initial request: The diagnosis has been confirmed by sleep lab evaluation. For continuation of therapy: The patient has experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a sleep disorder specialist or neurologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LUNSUMIO

## Products Affected

- Lunsumio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LUPKYNIS

## Products Affected

- Lupkynis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Use in combination with cyclophosphamide |
| **Required Medical Information** | For lupus nephritis: 1) patient is currently receiving background immunosuppressive therapy (e.g., mycophenolate mofetil, corticosteroids) for lupus nephritis, OR 2) patient has an intolerance or has a contraindication to background immunosuppressive therapy regimen for lupus nephritis. For lupus nephritis continuation: patient is receiving benefit from therapy and the benefit of continuing therapy outweighs the risk of worsening nephrotoxicity. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LUPRON PED

## Products Affected

- Lupron Depot-ped (1-month)
- Lupron Depot-ped (3-month)
- Lupron Depot-ped (6-month)

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For central precocious puberty (CPP): Patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, AND 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, AND 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients. |
| **Age Restrictions** | CPP: Patient must be less than 12 years old if female and less than 13 years old if male |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LUPRON-ENDOMETRIOSIS

## Products Affected

- Lupron Depot (1-month) INJ 3.75MG
- Lupron Depot (3-month) INJ 11.25MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Breast cancer, epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer, androgen receptor positive recurrent salivary gland tumor |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For retreatment of endometriosis, the requested drug is used in combination with norethindrone acetate. For uterine fibroids, patient must meet one of the following: 1) Diagnosis of anemia (e.g., hematocrit less than or equal to 30 percent and/or hemoglobin less than or equal to 10g/dL), OR 2) the requested medication will be used prior to surgery for uterine fibroids. For breast cancer, the requested drug is used for hormone receptor (HR)-positive disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Fibroids: 3 months (mo), max 6 mo total. Endometriosis: 6 mo, max 12 mo total. Others: Plan Year |
| **Other Criteria** | N/A |

# LUPRON-PROSTATE CA

## Products Affected

- Leuprolide Acetate INJ 22.5MG
- Lupron Depot (1-month) INJ 7.5MG
- Lupron Depot (3-month) INJ 22.5MG
- Lupron Depot (4-month)
- Lupron Depot (6-month)

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Malignant sex cord-stromal tumors |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LYBALVI

## Products Affected

- Lybalvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. For acute treatment of manic or mixed episodes associated with bipolar I disorder: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to brand Vraylar. For maintenance treatment of bipolar I disorder: the patient experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine, risperidone, ziprasidone. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LYNPARZA

**Products Affected**

- Lynparza TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent HER2-negative, BRCA 1/2-germline mutated breast cancer, recurrent or metastatic HER2-positive, BRCA 1/2-germline mutated breast cancer, uterine leiomyosarcoma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For recurrent or metastatic breast cancer: the disease is BRCA 1/2-germline mutated. For prostate cancer: 1) The patient has a BRCA mutation and the requested drug will be used in combination with abiraterone and either prednisone or prednisolone OR 2) The patient has progressed on prior treatment with an androgen receptor-directed therapy. For epithelial ovarian, fallopian tube, or primary peritoneal cancer: The requested drug is used for maintenance therapy for stage II-IV or recurrent disease who are in complete or partial response to chemotherapy. For uterine leiomyosarcoma: 1) the patient has had at least one prior therapy AND 2) the patient has BRCA-altered disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LYRICA CR

## Products Affected

- Lyrica Cr
- Pregabalin Er

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LYTGOBI

## Products Affected

- Lytgobi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Extrahepatic cholangiocarcinoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cholangiocarcinoma:1) patient has a diagnosis of unresectable, locally advanced or metastatic cholangiocarcinoma, 2) patient has received a previous treatment, AND 3) patient has a disease that has a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# LYVISPAH

## Products Affected

- Lyvispah

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient is unable to take oral solid dosage forms for any reason (e.g., difficulty swallowing tablets or capsules, requires administration via feeding tube). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MARGENZA

## Products Affected

- Margenza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MAVENCLAD AET

## Products Affected

- Mavenclad

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including relapsing-remitting disease and active secondary progressive disease]: Patient must have tried and failed or has a contraindication or intolerance to two of the following: brand Aubagio, Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone, brand Tecfidera, Vumerity (diroximel fumarate), Zeposia (ozanimod). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MAVYRET

**Products Affected**

- Mavyret

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C). |
| **Required Medical Information** | For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [CTP class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD-IDSA guidance |
| **Other Criteria** | N/A |

# MAYZENT AET

## Products Affected

- Mayzent
- Mayzent Starter Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease]: Patient must have tried and failed or has a contraindication or intolerance to two of the following: brand Aubagio, Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone, brand Tecfidera, Vumerity (diroximel fumarate), Zeposia (ozanimod). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MEKINIST

## Products Affected

- Mekinist

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with dabrafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For central nervous system (CNS) cancer (i.e., glioma, oligodendroglioma, astrocytoma, glioblastoma), non-small cell lung cancer, solid tumors, and anaplastic thyroid cancer: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used in combination with dabrafenib. For uveal melanoma: The requested drug will be used as a single agent. For ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: The requested drug will be used to treat persistent or recurrent disease. For gallbladder cancer, intrahepatic cholangiocarcinoma, and extrahepatic cholangiocarcinoma: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The disease is unresectable or metastatic, AND 3) The requested drug will be used in combination with dabrafenib. For papillary, follicular, and hurthle cell thyroid carcinoma: 1) The disease is positive for BRAF V600E mutation, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy, AND 3) The requested drug will be used in combination with dabrafenib. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MEKTOVI

**Products Affected**

- Mektovi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Adjuvant systemic therapy for cutaneous melanoma, Langerhans Cell Histiocytosis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used in combination with encorafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MEMANTINE

## Products Affected

- Memantine Hcl Titration Pak
- Memantine Hydrochloride SOLN 2MG/ML
- Memantine Hydrochloride TABS
- Memantine Hydrochloride Er
- Namenda TABS 5MG
- Namenda Titration Pak
- Namenda Xr

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | This prior authorization only applies to patients less than 30 years of age. |

# MEPRON AET

## Products Affected

- Atovaquone SUSP
- Mepron SUSP

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Babesiosis, Toxoplasmosis, Pneumocystis jirovecii pneumonia prophylaxis in pediatric patients, mild-to-moderate Pneumocystis jirovecii pneumonia treatment in pediatric patients. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of mild-to-moderate Pneumocystis jiroveci pneumonia (PCP): the patient had an intolerance or has a contraindication to sulfamethoxazole/trimethoprim (SMX-TMP). For the prevention of PCP and primary toxoplasmosis prophylaxis indications: A) the patient had an intolerance or has a contraindication to SMX-TMP, AND B) the patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 3 months. For secondary toxoplasmosis prophylaxis: the patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 6 months. For babesiosis treatment: the requested drug is used concurrently with azithromycin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Secondary toxoplasmosis prophylaxis: 6 months, All other indications: 3 months |
| **Other Criteria** | N/A |

# MEPSEVII

## Products Affected

- Mepsevii

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For mucopolysaccharidosis VII (Sly syndrome): Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucuronidase enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# METFORMIN ER

## Products Affected

- Glumetza
- Metformin Hydrochloride Er TB24 1000MG, 500MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an intolerance with a 4-week trial of generic Glucophage XR. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# METHYLTESTOSTERONE

## Products Affected

- Methitest
- Methyltestosterone CAPS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to alternative testosterone products (e.g., topical testosterone, transdermal testosterone, injectable testosterone). For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MIACALCIN AET

## Products Affected

- Calcitonin Salmon INJ
- Miacalcin INJ

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hypercalcemia: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following: generic zoledronic acid, generic pamidronate, generic etidronate, generic cinacalcet, Xgeva (denosumab). For Paget's Disease: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following: generic zoledronic acid, generic alendronate, generic etidronate, generic pamidronate, generic risedronate. For postmenopausal osteoporosis: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following: generic zoledronic acid, generic calcitonin spray, generic alendronate, generic risedronate, Forteo (teriparatide), Prolia (denosumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MICO-ZN-PETR OINT

## Products Affected

- Miconazole Nitrate/zinc Oxide/white Petrolatum
- Vusion

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The presence of candidal infection has been confirmed by microscopic evaluation (microscopic evidence of pseudohyphae and/or budding yeast) prior to initiating treatment. |
| **Age Restrictions** | Pediatric patient 4 weeks of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# MIGLUSTAT

## Products Affected

- Miglustat
- Yargesa
- Zavesca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For type 1 Gaucher disease (GD1): Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MODAFINIL

## Products Affected

- Modafinil TABS
- Provigil

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For excessive sleepiness associated with narcolepsy: The diagnosis has been confirmed by sleep lab evaluation. For excessive sleepiness associated with obstructive sleep apnea (OSA): The diagnosis has been confirmed by polysomnography. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MONJUVI

**Products Affected**

- Monjuvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | HIV-related B-cell lymphoma, refractory/relapsed/progressive follicular lymphoma, monomorphic post-transplant lymphoproliferative disorder (B-cell type), high-grade B-cell lymphoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For diffuse large B-cell lymphoma (DLBCL) not otherwise specified, HIV-related B-cell lymphoma, monomorphic post-transplant lymphoproliferative disorder (B-cell type), high-grade B-cell lymphoma, diffuse large B-cell lymphoma (DLBCL) not otherwise specified including DLBCL arising from low grade lymphoma: 1) the patient has relapsed or refractory disease, AND 2) the patient is not eligible for autologous stem cell transplant (ASCT). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MOTEGRITY AET

**Products Affected**

- Motegrity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum. |
| **Required Medical Information** | Patient experienced an inadequate treatment response, intolerance, or has a contraindication to Amitiza (lubiprostone) and Linzess (linaclotide). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MOUNJARO

## Products Affected

- Mounjaro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | The Prior Authorization only applies to patients whose claim is not submitted with an ICD-10 code indicating a diagnosis of type 2 diabetes mellitus OR to patients who do not have a history of an antidiabetic drug (EXCLUDING glucagon-like peptide receptor agonists [GLP-1 RAs] and combination glucose-dependent insulinotropic polypeptide [GIP] and GLP-1 RAs). |

# MOZOBIL

## Products Affected

- Mozobil
- Plerixafor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# MULPLETA

**Products Affected**

- Mulpleta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For thrombocytopenia in patients with chronic liver disease: Untransfused platelet count prior to a scheduled procedure is less than 50,000/mcL. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# MVASI

**Products Affected**

- Mvasi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Ampullary adenocarcinoma, breast cancer, central nervous system (CNS) cancers, malignant pleural mesothelioma, malignant peritoneal mesothelioma, pericardial mesothelioma, tunica vaginalis testis mesothelioma, soft tissue sarcomas, uterine neoplasms, endometrial carcinoma, vulvar cancers, small bowel adenocarcinoma, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications except ophthalmic-related disorders: The patient had an intolerable adverse event to Zirabev and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# MYALEPT

## Products Affected

- Myalept

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Human immunodeficiency virus (HIV) - related lipodystrophy. Generalized obesity not associated with generalized lipodystrophy. |
| **Required Medical Information** | For lipodystrophy patient meets all of the following: 1) Patient has a diagnosis of congenital generalized lipodystrophy (i.e., Berardinelli-Seip syndrome) OR acquired generalized lipodystrophy (i.e., Lawrence syndrome), 2) Patient has leptin deficiency confirmed by laboratory testing, AND 3) Patient has at least one complication of lipodystrophy (e.g., diabetes mellitus, hypertriglyceridemia, increased fasting insulin levels). For lipodystrophy renewal, patient has experienced an improvement from baseline in metabolic control (e.g., improved glycemic control, decrease in triglycerides, decrease in hepatic enzyme levels). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MYCAPSSA

## Products Affected

- Mycapssa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MYFEMBREE

## Products Affected

- Myfembree

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and moderate to severe pain associated with endometriosis in a premenopausal patient: the patient has not already received greater than or equal to 24 months of treatment with the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months, max 24 months total |
| **Other Criteria** | N/A |

# MYLOTARG

## Products Affected

- Mylotarg

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Acute promyelocytic leukemia (APL) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MYOBLOC

**Products Affected**

- Myobloc

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Primary axillary hyperhidrosis, palmar hyperhidrosis. |
| **Exclusion Criteria** | Cosmetic use. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# MYTESI AET

## Products Affected

- Mytesi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For non-infectious diarrhea in a patient with human immunodeficiency virus/acquired immunodeficiency virus (HIV/AIDS): 1) Patient is receiving anti-retroviral therapy, AND 2) Patient has a history of diarrhea for one month or more characterized by a) persistently loose stools despite regular use of anti-diarrheal medication (ADM) (e.g., loperamide, diphenoxylate, bismuth subsalicylate) or b) one or more watery bowel movements per day without regular ADM use, AND 3) Patient has a negative gastrointestinal (GI) culture or stool test for a) bacteria and b) bacterial toxin and c) ova and parasites and d) viruses, AND 4) Other GI diseases associated with diarrhea (e.g., ulcerative colitis, Crohn's disease, celiac sprue [gluten-enteropathy], chronic pancreatitis, malabsorption) have been ruled out. For continuation of therapy, patient must have experienced symptomatic relief with treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# NAGLAZYME

## Products Affected

- Naglazyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Mucopolysaccharidosis VI (Maroteaux-Lamy syndrome) was confirmed by an enzyme assay demonstrating a deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NAPROXEN-ESOMEPRAZOLE

## Products Affected

- Naproxen/esomeprazole Magnesium
- Vimovo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response or intolerance to two different regimens containing any combination of a nonsteroidal anti-inflammatory drug (NSAID) and an acid blocker from any of the following drug classes: H2-receptor antagonist (H2RA), proton pump inhibitor (PPI). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NAYZILAM

## Products Affected

- Nayzilam

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NEMLUVIO

**Products Affected**

- Nemluvio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For prurigo nodularis (PN), initial therapy: Patient has had an inadequate treatment response to a topical corticosteroid OR topical corticosteroids are not advisable for the patient. For PN, continuation of therapy: Patient achieved or maintained a positive clinical response. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | PN, initial: 6 months, PN, continuation: Plan Year |
| **Other Criteria** | N/A |

# NERLYNX

## Products Affected

- Nerlynx

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer, brain metastases from HER2-positive breast cancer. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NEULASTA

## Products Affected

- Fulphila
- Fylnetra
- Neulasta
- Neulasta Onpro Kit
- Nyvepria
- Udenyca
- Udenyca Onbody
- Ziextenzo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Stem cell transplantation-related indications |
| **Exclusion Criteria** | Use of the requested product less than 24 hours before or after chemotherapy. |
| **Required Medical Information** | For prophylaxis of myelosuppressive chemotherapy-induced febrile neutropenia: the patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, and 2) Patient is currently receiving or will be receiving treatment with myelosuppressive anti-cancer therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# NEUPOGEN

**Products Affected**

- Neupogen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Neutropenia in myelodysplastic syndromes (MDS), agranulocytosis, neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia, neutropenia related to renal transplantation |
| **Exclusion Criteria** | Use of the requested product within 24 hours prior to or following chemotherapy. |
| **Required Medical Information** | For prophylaxis or treatment of myelosuppressive chemotherapy-induced febrile neutropenia (FN), patient must meet all of the following: 1) Patient has a solid tumor or non-myeloid cancer AND 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# NEXAVAR

## Products Affected

- Nexavar
- Sorafenib Tosylate TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Acute myeloid leukemia, soft tissue sarcoma (angiosarcoma, desmoid tumors/aggressive fibromatosis, and solitary fibrous tumor subtypes), gastrointestinal stromal tumor, medullary thyroid carcinoma, osteosarcoma, recurrent chordoma, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute myeloid leukemia: the disease is FMS-like tyrosine kinase 3-internal tandem duplication (FLT3-ITD) mutation-positive AND either of the following is met (1 OR 2): 1) the requested drug will be used as maintenance therapy after hematopoietic stem cell transplant, OR 2) the requested drug is used in combination with azacitidine or decitabine for low-intensity treatment induction or post-induction therapy AND either a) the patient has is 60 years of age or older or b) the disease is relapsed/refractory. For thyroid carcinoma: histology is follicular, papillary, Hurthle cell or medullary. For gastrointestinal stromal tumor (GIST): the patient meets either of the following: 1) the disease is unresectable, recurrent/progressive, or metastatic AND the patient has failed on an FDA-approved therapy (e.g., imatinib, sunitinib, regorafenib, ripretinib) OR 2) the requested drug is being used for palliation of symptoms if previously tolerated and effective. For renal cell carcinoma: the disease is advanced. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia: 1) the disease has a FLT3 rearrangement AND 2) the disease is in chronic or blast phase. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | N/A |

# NEXIUM IV

## Products Affected

- Nexium I.v. INJ 40MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For gastroesophageal reflux disease (GERD) with erosive esophagitis (EE): The patient has an intolerance or a contraindication to OR has experienced an inadequate treatment response to a one-month trial of TWO of the following formulary generic proton pump inhibitors (PPIs): lansoprazole, omeprazole, omeprazole/bicarbonate, pantoprazole, esomeprazole sodium, or esomeprazole magnesium. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NEXVIAZYME

## Products Affected

- Nexviazyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For late-onset Pompe disease: diagnosis was confirmed by an enzyme assay demonstrating a deficiency of acid alpha-glucosidase (GAA) enzyme activity or by genetic testing. |
| **Age Restrictions** | 1 year of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NGENLA AET

## Products Affected

- Ngenla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Pediatric patients with closed epiphyses |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Genotropin. If using target medication for a medically accepted indication not shared by Genotropin, then no trial of Genotropin is required for that target medication. For pediatric growth hormone deficiency (GHD), initial: A) Patient (pt) has pre-treatment (pre-tx) 1-year height (ht) velocity more than 2 standard deviations (SD) below mean OR a pre-tx ht more than 2 SD below mean and a 1-year ht velocity more than 1 SD below mean AND pt meets any of the following: 1) failed 2 pre-tx growth hormone (GH) stimulation tests (peak below 10 ng/mL), 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 OR B) Pt was diagnosed with GHD as a neonate. For pediatric GHD, continuation of therapy: Pt is experiencing improvement. |
| **Age Restrictions** | 3 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NINLARO

## Products Affected

- Ninlaro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Relapsed/refractory systemic light chain amyloidosis, Waldenstrom macroglobulinemia, lymphoplasmacytic lymphoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NITISINONE

## Products Affected

- Nitisinone
- Orfadin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hereditary tyrosinemia type 1 (HT-1): Diagnosis of HT-1 is confirmed by one of the following: 1) biochemical testing (e.g., detection of succinylacetone in urine) OR 2) DNA testing (mutation analysis). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NITYR

## Products Affected

- Nityr

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hereditary tyrosinemia type 1 (HT-1): Diagnosis of HT-1 is confirmed by one of the following: 1) biochemical testing (e.g., detection of succinylacetone in urine) OR 2) DNA testing (mutation analysis). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NOCDURNA AET

## Products Affected

- Nocdurna

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Hyponatremia or a history of hyponatremia, polydipsia, concomitant use with loop diuretics or systemic or inhaled glucocorticoids, estimated glomerular filtration rate below 50 mL/min/1.73 m2, syndrome of inappropriate antidiuretic hormone secretion (SIADH), during illnesses that can cause fluid or electrolyte imbalance, heart failure, uncontrolled hypertension. |
| **Required Medical Information** | For nocturia due to nocturnal polyuria: 1) the diagnosis has been confirmed with a 24-hour urine collection, AND 2) patient is awakening at least 2 times per night to void.<br>For nocturia due to nocturnal polyuria (continuation therapy): nocturnal polyuria is stable or showing clinical improvement. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial approval: 3 months, Renewal: Plan Year |
| **Other Criteria** | N/A |

# NORTHERA

## Products Affected

- Droxidopa
- Northera

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For neurogenic orthostatic hypotension (nOH): Prior to initial therapy, patient has a persistent, consistent decrease in systolic blood pressure of at least 20 mmHg OR decrease in diastolic blood pressure of at least 10 mmHg within 3 minutes of standing or head-up tilt test. For continuation of therapy for nOH, patient must experience a sustained reduction in symptoms of nOH (i.e., decrease in dizziness, lightheadedness, or feeling faint). For both initial and continuation of therapy for nOH, the requested drug will be used for patients with neurogenic orthostatic hypotension associated with one of the following diagnoses: 1) primary autonomic failure due to Parkinson's disease, multiple system atrophy, or pure autonomic failure, OR 2) dopamine beta-hydroxylase deficiency, OR 3) non-diabetic autonomic neuropathy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# NOURIANZ AET

**Products Affected**

- Nourianz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Parkinson's disease (PD) with off episodes: 1) The patient has experienced an inadequate treatment response to a one month trial each of TWO of the following in combination with levodopa/carbidopa: a dopamine agonist (e.g., ropinirole, pramipexole), a catechol-O-methyl transferase (COMT) inhibitor (e.g., entacapone), or a monoamine oxidase B (MAO-B) inhibitor (e.g., rasagiline, selegiline) OR 2) The patient has experienced an intolerance to or has a contraindication that would prohibit a trial of each of the following treatments: a dopamine agonist (e.g., ropinirole, pramipexole), a catechol-O-methyl transferase (COMT) inhibitor (e.g., entacapone), and a monoamine oxidase B (MAO-B) inhibitor (e.g., rasagiline, selegiline). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NOXAFIL POWDER

## Products Affected

- Noxafil PACK

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will be used orally. For prophylaxis of invasive Aspergillus and Candida infections: patient weighs 40 kilograms or less. |
| **Age Restrictions** | 2 to less than 18 years of age |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# NOXAFIL SUSP

## Products Affected

- Noxafil SUSP

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will be used orally. For treatment of oropharyngeal candidiasis: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to fluconazole. |
| **Age Restrictions** | 13 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Oropharyngeal candidiasis: 1 month. All other indications: 6 months |
| **Other Criteria** | N/A |

# NP GROWTH HORMONE

## Products Affected

- Humatrope INJ 12MG, 24MG, 6MG
- Norditropin Flexpro
- Nutropin Aq Nuspin 10
- Nutropin Aq Nuspin 20
- Nutropin Aq Nuspin 5
- Omnitrope
- Saizenprep Reconstitutionkit
- Zomacton

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Pediatric patients with closed epiphyses |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Genotropin. If using target medication for a medically accepted indication not shared by Genotropin, then no trial of Genotropin is required for that target medication. 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 (TS): 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, nephrologist, infectious disease specialist, gastroenterologist/nutritional support specialist, or geneticist. |

| | |
|---|---|
| **Coverage Duration** | Plan Year |
| **Other Criteria** | 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/m2 and high pretest probability of GHD [e.g., acquired structural abnormalities] or BMI less than 25 kg/m2, or d) GST [peak GH level less than or equal to 1 ng/ml] in pt with BMI 25-30 kg/m2 and low pretest probability of GHD or BMI greater than 30 kg/m2), 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. |

# NPLATE

**Products Affected**

- Nplate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For immune thrombocytopenia (ITP) (new starts): 1) Patient has had an inadequate response or is intolerant to a prior therapy such as corticosteroids or immunoglobulins, AND 2) Untransfused platelet count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000 to 50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes patient to trauma). For ITP (continuation of therapy): Patient has platelet count response to the requested drug with one of the following: 1) Current platelet count is less than or equal to 200,000/mcL OR 2) Current platelet count is greater than 200,000/mcL and less than or equal to 400,000/mcL and dosing will be adjusted to a platelet count sufficient to avoid clinically important bleeding. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | For ITP: Initial: 6 months, Reauthorization: Plan Year For HSARS: Plan Year |
| **Other Criteria** | N/A |

# NUBEQA

## Products Affected

- Nubeqa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NUCALA

## Products Affected

- Nucala

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For severe asthma, initial therapy: 1) Either a) Patient has baseline blood eosinophil count of at least 150 cells per microliter OR b) Patient is dependent on systemic corticosteroids, and 2) Patient has a history of severe asthma despite current treatment with both of the following medications: a) medium-to-high-dose inhaled corticosteroid and b) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For severe asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For eosinophilic granulomatosis with polyangiitis (EGPA), initial therapy: Patient has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10 percent. For EGPA, continuation of therapy: Patient has a beneficial response to treatment with the requested drug, as demonstrated by any of the following: 1) a reduction in the frequency of relapses, 2) a reduction in the daily oral corticosteroid dose, or 3) no active vasculitis. For hypereosinophilic syndrome (HES), initial therapy: 1) Patient has had HES for greater than or equal to 6 months, 2) Patient has HES without an identifiable non-hematologic secondary cause, 3) Patient does not have FIP1L1-PDGFRA kinase-positive HES, 4) Patient has a history or presence of a blood eosinophil count of at least 1000 cells per microliter, AND 5) Patient has been on a stable dose of at least one HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy). For HES, continuation of therapy: Patient has a beneficial response to treatment as demonstrated by a reduction in HES flares. |
| **Age Restrictions** | Asthma: 6 years of age or older, EGPA and CRSwNP: 18 years of age or older, HES: 12 years of age or older |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | For chronic rhinosinusitis with nasal polyps (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) The patient has experienced inadequate treatment response to Xhance (fluticasone). |

# NUEDEXTA

## Products Affected

- Nuedexta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NULIBRY

## Products Affected

- Nulibry

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For molybdenum cofactor deficiency (MoCD) Type A: 1) Diagnosis of MoCD Type A is confirmed by genetic testing OR 2) Patient has a presumed diagnosis of MoCD Type A based on clinical presentation and genetic test results are pending. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Presumed Diagnosis: 3 months, Confirmed Diagnosis: Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# NUPLAZID

## Products Affected

- Nuplazid CAPS
- Nuplazid TABS 10MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hallucinations and delusions associated with Parkinson's disease psychosis, the diagnosis of Parkinson's disease must be made prior to the onset of psychotic symptoms. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# NURTEC

## Products Affected

- Nurtec

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute migraine treatment: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to one triptan 5-HT1 receptor agonist . Preventive treatment of migraine, initial: The patient meets either of the following: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants. Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug, and the patient had a reduction in migraine days per month from baseline. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Preventive treatment of migraine - initial: 3 months, All other indications: Plan Year |
| **Other Criteria** | N/A |

# OCALIVA

## Products Affected

- Ocaliva

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary biliary cholangitis (PBC) without cirrhosis or with compensated cirrhosis without evidence of portal hypertension: For initial therapy, 1) Diagnosis of PBC (previously known as primary biliary cirrhosis) is confirmed by at least two of the following: A) Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration, B) Presence of antimitochondrial antibodies (AMA) (titer greater than 1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies ANA (eg, anti-gp210, anti-sp100), or C) Histologic evidence of PBC on liver biopsy (eg, non-suppurative inflammation and destruction of interlobular and septal bile ducts) and 2) Patient has an elevated serum ALP level prior to initiation of therapy with the requested drug and meets one of the following requirements: A) Inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol and the patient will continue concomitant therapy with UDCA/ursodiol, or B) Intolerance to UDCA/ursodiol. For continuation of therapy for PBC: patient achieved or maintained a clinical benefit from Ocaliva therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months. Continuation: Plan Year. |
| **Other Criteria** | N/A |

# OCREVUS

## Products Affected

- Ocrevus

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OCTREOTIDE

## Products Affected

- Octreotide Acetate INJ 1000MCG/ML, 100MCG/ML, 200MCG/ML, 500MCG/ML, 50MCG/ML
- Sandostatin INJ 100MCG/ML, 500MCG/ML, 50MCG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Tumor control of thymomas and thymic carcinomas. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. For tumor control of thymomas and thymic carcinomas: The requested drug will be used for any of the following: 1) locally advanced or metastatic disease, 2) postoperatively following tumor resection. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ODACTRA

## Products Affected

- Odactra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy. History of eosinophilic esophagitis. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 12 to 65 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist or immunologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ODOMZO

## Products Affected

- Odomzo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OFEV

## Products Affected

- Ofev

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For idiopathic pulmonary fibrosis (new starts only): 1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern, OR 2) HRCT study of the chest reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported either by a lung biopsy or by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OGSIVEO

## Products Affected

- Ogsiveo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OHTUVAYRE

## Products Affected

- Ohtuvayre

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic obstructive pulmonary disease (COPD): the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following: Breo Ellipta (fluticasone/vilanterol), fluticasone/salmeterol, Incruse Ellipta (umeclidinium), Anoro Ellipta (umeclidinium/vilanterol), Bevespi (glycopyrrolate/formoterol), Serevent Diskus (salmeterol), Trelegy Ellipta (fluticasone/umeclidinium/vilanterol), Wixela. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# OJEMDA

**Products Affected**

- Ojemda

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For relapsed or refractory pediatric low-grade glioma (LGG): the patient's tumor is positive for either a) BRAF fusion or rearrangement OR b) BRAF V600 mutation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OJJAARA

## Products Affected

- Ojjaara

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OLUMIANT

## Products Affected

- Olumiant

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For severe alopecia areata, initial therapy: 1) patient has at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) AND 2) patient does not have primarily diffuse pattern alopecia (characterized by diffuse hair shedding) or other forms of alopecia (e.g., androgenetic alopecia, trichotillomania, telogen effluvium, chemotherapy-induced hair loss). For severe alopecia areata, continuation of therapy: patient has achieved or maintained a positive clinical response as evidenced by an improvement in signs and symptoms of the condition from baseline (e.g., increased scalp hair coverage). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OMVOH

## Products Affected

- Omvoh

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active ulcerative colitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ONCASPAR

## Products Affected

- Oncaspar

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Extranodal natural killer/T-cell lymphoma, hepatosplenic T-cell lymphoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For extranodal natural killer/T-cell lymphoma, acute lymphoblastic leukemia, and hepatosplenic T-cell lymphoma: the requested drug must be used in conjunction with multi-agent chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ONGENTYS AET

## Products Affected

- Ongentys

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Parkinson's disease (PD) with off episodes: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a one month trial of generic carbidopa/levodopa/entacapone or generic entacapone used in combination with a generic levodopa/carbidopa product. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ONIVYDE

## Products Affected

- Onivyde

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Ampullary adenocarcinoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pancreatic adenocarcinoma: 1) the requested drug will be used in combination with fluorouracil and leucovorin, OR 2) the requested drug will be used in combination with oxaliplatin, fluorouracil, and leucovorin. For ampullary adenocarcinoma: 1) the requested drug will be used as a subsequent therapy, AND 2) the requested drug will be used in combination with fluorouracil and leucovorin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ONUREG

## Products Affected

- Onureg

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OPDIVO

## Products Affected

- Opdivo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OPDUALAG

## Products Affected

- Opdualag

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OPFOLDA

## Products Affected

- Opfolda

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For late-onset Pompe disease: 1) Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of acid alpha-glucosidase (GAA) enzyme activity or by genetic testing AND 2) The requested drug will be used in combination with Pombiliti (cipaglucosidase alfa-atga) AND 3) Patient meets BOTH of the following: A) weighs at least 40 kilograms (kg), B) is not improving on their current enzyme replacement therapy (ERT). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OPSUMIT

## Products Affected

- Opsumit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OPSYNVI

## Products Affected

- Opsynvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OPZELURA

## Products Affected

- Opzelura

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in a non-immunocompromised patient, initial therapy: 1) The requested drug will be used on sensitive areas (e.g., face, genitals, or skin folds) and the patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor, OR 2) The requested drug will be used on non-sensitive (or remaining) skin areas and the patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor or a medium or higher potency topical corticosteroid. For the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in a non-immunocompromised patient, continuation of therapy: The patient achieved or maintained positive clinical response. For the topical treatment of nonsegmental vitiligo (NSV): The requested drug will be applied to affected areas of 10 percent or less body surface area (BSA). For the topical treatment of nonsegmental vitiligo, continuation of therapy: The patient achieved or maintained meaningful repigmentation. |
| **Age Restrictions** | AD, NSV: 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | AD, Initial: 3 months, NSV, Initial: 7 months, AD, NSV Continuation: Plan Year |
| **Other Criteria** | N/A |

# ORACEA AET

## Products Affected

- Doxycycline CPDR
- Oracea

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a formulary generic topical metronidazole. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ORALAIR

## Products Affected

- Oralair

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy. History of eosinophilic esophagitis. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 5 to 65 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist or immunologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ORAL-INTRANASAL FENTANYL

## Products Affected

- Fentanyl Citrate TABS 200MCG, 400MCG, 600MCG, 800MCG
- Fentanyl Citrate Oral Transmucosal
- Fentora TABS 100MCG, 200MCG, 400MCG, 600MCG, 800MCG
- Subsys

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) The requested drug is indicated for the treatment of breakthrough cancer-related pain only. The requested drug is being prescribed for the management of breakthrough pain in a cancer patient with underlying cancer pain AND 2) The International Classification of Diseases (ICD) diagnosis code provided supports the cancer-related diagnosis. [Note: For drug coverage approval, ICD diagnosis code provided MUST support the cancer-related diagnosis.] AND 3) The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying cancer pain AND 4) The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their current opioid use history. [Note: Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 60 mg of oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for one week or longer.]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ORENCIA

## Products Affected

- Orencia
- Orencia Clickject

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For moderately to severely active polyarticular juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For an adult with active psoriatic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ORENITRAM

## Products Affected

- Orenitram
- Orenitram Titration Kit Month 1
- Orenitram Titration Kit Month 2
- Orenitram Titration Kit Month 3

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ORGOVYX

## Products Affected

- Orgovyx

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ORIAHNN

## Products Affected

- Oriahnn

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in a premenopausal patient: the patient has not already received greater than or equal to 24 months of treatment with any elagolix-containing drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months, max 24 months total |
| **Other Criteria** | N/A |

# ORILISSA

## Products Affected

- Orilissa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe pain associated with endometriosis: the patient has not already received greater than or equal to 24 months of treatment with any elagolix-containing drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months, max 24 months total |
| **Other Criteria** | N/A |

# ORKAMBI

## Products Affected

- Orkambi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor. |
| **Age Restrictions** | 1 year of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ORLADEYO

## Products Affected

- Orladeyo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the prevention of acute angioedema attacks due to hereditary angioedema (HAE): The patient meets either of the following: 1) the patient has hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has hereditary angioedema with normal C1 inhibitor confirmed by laboratory testing and either of the following: a) 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 b) 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. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ORSERDU

## Products Affected

- Orserdu

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: 1) the disease is estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER2)-negative, and ESR1 mutated AND 2) the patient meets either of the following: a) the disease is advanced, recurrent, or metastatic AND the patient has disease progression following at least one line of endocrine therapy OR b) the disease had no response to preoperative systemic therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OSPHENA

## Products Affected

- Osphena

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OTEZLA

## Products Affected

- Otezla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OXANDROLONE

## Products Affected

- Oxandrolone TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Cachexia associated with AIDS (HIV wasting). To enhance growth in patients with Turners Syndrome |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Turners Syndrome: Plan Year, All other diagnoses: 6 months |
| **Other Criteria** | Coverage will be denied if request is for an indication excluded from Medicare Part D. |

# OXAZEPAM - 65

## Products Affected

- Oxazepam

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: 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.) For the management of anxiety disorders, anxiety associated with depression, and the management of anxiety, tension, agitation and irritability in older patients: 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). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Short-term relief anxiety-1 month, Anxiety Disorders-4 months, Alcohol Withdrawal-Plan Year |
| **Other Criteria** | This Prior Authorization only applies to patients 65 years of age or older. |

# OXBRYTA

## Products Affected

- Oxbryta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 4 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OXERVATE

## Products Affected

- Oxervate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist |
| **Coverage Duration** | 8 weeks |
| **Other Criteria** | N/A |

# OXLUMO

## Products Affected

- Oxlumo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary hyperoxaluria type 1 (PH1): diagnosis has been confirmed by a molecular genetic test showing a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene or liver enzyme analysis demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity. For continuation of therapy: the patient has experienced decreased or normalized levels of either of the following since initiating therapy: 1) urinary oxalate, 2) plasma oxalate. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OXYCONTIN AET

## Products Affected

- Oxycodone Hcl Er T12A
- Oxycodone Hydrochloride Er T12A 10MG, 20MG
- Oxycontin T12A

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe enough to require daily, around-the-clock, long-term opioid treatment in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) The request is for continuation of therapy for a patient who has been receiving an extended-release opioid for at least 30 days OR the patient has severe, continuous pain and the patient has taken an immediate-release opioid for at least one week AND 5) For chronic pain except pain associated with cancer, sickle cell disease, a terminal condition, or palliative care: the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two alternative formulary long-acting opioids such as Hysingla ER, controlled-release morphine, fentanyl patches. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# OZEMPIC

## Products Affected

- Ozempic

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | The Prior Authorization only applies to patients whose claim is not submitted with an ICD-10 code indicating a diagnosis of type 2 diabetes mellitus OR to patients who do not have a history of an antidiabetic drug (EXCLUDING glucagon-like peptide receptor agonists [GLP-1 RAs] and combination glucose-dependent insulinotropic polypeptide [GIP] and GLP-1 RAs). |

# PADCEV

## Products Affected

- Padcev

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For urothelial carcinoma, the requested drug will be used for treatment of any of the following: a) locally advanced or metastatic urothelial carcinoma, b) urothelial carcinoma of the bladder with muscle invasive local recurrence or persistent disease in a preserved bladder, c) urothelial carcinoma of the bladder with metastatic or local recurrence post cystectomy, d) recurrent primary carcinoma of the urethra, or e) stage II-IV urothelial carcinoma of the bladder. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PALFORZIA

## Products Affected

- Palforzia Initial Dose Escalation
- Palforzia Level 1
- Palforzia Level 10
- Palforzia Level 11 (maintenance)
- Palforzia Level 11 (titration)
- Palforzia Level 2
- Palforzia Level 3
- Palforzia Level 4
- Palforzia Level 5
- Palforzia Level 6
- Palforzia Level 7
- Palforzia Level 8
- Palforzia Level 9

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Uncontrolled asthma. History of eosinophilic esophagitis. Other eosinophilic gastrointestinal disease. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Up-Dosing and Maintenance phase of treatment: 1 year of age or older. Otherwise: 1 to 17 years of age. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist or immunologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PALYNZIQ AET

## Products Affected

- Palynziq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For phenylketonuria (PKU): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to sapropterin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PANRETIN

## Products Affected

- Panretin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Topical treatment of cutaneous lesions in patients with non-AIDS-related Kaposi sarcoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PEGASYS

## Products Affected

- Pegasys

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | 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, initial treatment during pregnancy for chronic myeloid leukemia. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic hepatitis C: Hepatitis C virus (HCV) confirmed by presence of hepatitis C virus HCV RNA in serum prior to starting treatment and the planned treatment regimen. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | HCV: 12-48wks. Criteria applied consistent w/current AASLD/IDSA guidance. HBV: 48wks. Other: Plan Yr |
| **Other Criteria** | N/A |

# PEMAZYRE

## Products Affected

- Pemazyre

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PERFOROMIST AET

## Products Affected

- Formoterol Fumarate NEBU
- Perforomist

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Bevespi Aerosphere (glycopyrrolate/formoterol) AND Serevent Diskus (salmeterol). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# PERJETA

## Products Affected

- Perjeta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma), recurrent HER2-positive salivary gland tumors, brain metastases from HER2-positive breast cancer, unresectable or metastatic HER2-positive hepatobiliary cancers (gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For colorectal cancer (including appendiceal adenocarcinoma): 1) the disease is HER2-amplified and RAS and BRAF wild-type AND 2) the requested drug is used in combination with trastuzumab AND 3) the patient has not had previous treatment with a HER2 inhibitor. For HER2-positive recurrent salivary gland tumors, brain metastases from HER2 positive breast cancer, and unresectable or metastatic HER2-positive hepatobiliary cancer (gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma): the requested drug is used in combination with trastuzumab. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PHENYLBUTYRATE

## Products Affected

- Buphenyl
- Olpruva
- Pheburane
- Sodium Phenylbutyrate POWD 3GM/TSP
- Sodium Phenylbutyrate TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For urea cycle disorders (UCD): Diagnosis of UCD was confirmed by enzymatic, biochemical, or genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PHESGO

## Products Affected

- Phesgo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PIASKY

## Products Affected

- Piasky

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For paroxysmal nocturnal hemoglobinuria (PNH) (initial): 1) The diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) AND 2) Flow cytometry is used to demonstrate GPI-AP deficiency. For PNH (continuation): 1) There is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) The patient has demonstrated a positive response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# PIQRAY

## Products Affected

- Piqray 200mg Daily Dose
- Piqray 250mg Daily Dose
- Piqray 300mg Daily Dose

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated breast cancer in combination with fulvestrant. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PLEGRIDY AET

## Products Affected

- Plegridy
- Plegridy Starter Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease]: Patient must have tried and failed or has a contraindication or intolerance to two of the following: brand Aubagio, Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone, brand Tecfidera, Vumerity (diroximel fumarate), Zeposia (ozanimod). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# POLIVY

## Products Affected

- Polivy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, monomorphic post-transplant lymphoproliferative disorders (B-cell type), acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specified, and AIDS-related plasmablastic lymphoma), and follicular lymphoma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# POMALYST

## Products Affected

- Pomalyst

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Relapsed/refractory systemic light chain amyloidosis, primary central nervous system (CNS) lymphoma, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For multiple myeloma, patient has previously received at least two prior therapies for multiple myeloma, including an immunomodulatory agent AND a proteasome inhibitor. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# POMBILITI

## Products Affected

- Pombiliti

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For late-onset Pompe disease: 1) Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of acid alpha-glucosidase (GAA) enzyme activity or by genetic testing AND 2) The requested drug will be used in combination with Opfolda (miglustat) AND 3) Patient meets BOTH of the following: A) weighs at least 40 kilograms (kg), B) is not improving on their current enzyme replacement therapy (ERT). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PONVORY AET

## Products Affected

- Ponvory
- Ponvory 14-day Starter Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease]: Patient must have tried and failed or has a contraindication or intolerance to two of the following: brand Aubagio, Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone, brand Tecfidera, Vumerity (diroximel fumarate), Zeposia (ozanimod). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PORTRAZZA

## Products Affected

- Portrazza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# POSACONAZOLE

## Products Affected

- Noxafil TBEC
- Posaconazole Dr

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will be used orally. For prophylaxis of invasive Aspergillus and Candida infections: patient weighs greater than 40 kilograms. |
| **Age Restrictions** | Treatment of Invasive Aspergillosis: 13 years of age or older, Prophylaxis of Invasive Aspergillus and Candida Infections: 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# POTELIGEO

## Products Affected

- Poteligeo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Adult T-cell leukemia/lymphoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PRALUENT

## Products Affected

- Praluent

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PREGABALIN

## Products Affected

- Lyrica
- Pregabalin CAPS
- Pregabalin SOLN

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Cancer-related neuropathic pain, cancer treatment-related neuropathic pain |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the management of postherpetic neuralgia, the management of neuropathic pain associated with diabetic peripheral neuropathy, cancer-related neuropathic pain, and cancer treatment-related neuropathic pain: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PRETOMANID AET

## Products Affected

- Pretomanid

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For tuberculosis (TB), patient meets ALL of the following: 1) the requested drug is being used for treatment of pulmonary extensively drug resistant (XDR), treatment intolerant or nonresponsive multidrug resistant (MDR) tuberculosis, AND 2) the requested drug is used in combination with bedaquiline and linezolid. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PREVYMIS

## Products Affected

- Prevymis TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For prophylaxis of cytomegalovirus (CMV) infection or disease in hematopoietic stem cell transplant (HSCT): 1) the patient is CMV-seropositive, AND 2) the patient is a recipient of an allogeneic HSCT. For prophylaxis of CMV disease in kidney transplant: 1) the patient is CMV-seronegative, AND 2) the patient is a high risk recipient of kidney transplant. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 7 months |
| **Other Criteria** | N/A |

# PROAIR DIGIHALER

## Products Affected

- Proair Digihaler

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD) in an adult patient. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to albuterol HFA. |
| **Age Restrictions** | Bronchospasm and exercise-induced bronchospasm: 4 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PROCYSBI

## Products Affected

- Procysbi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For nephropathic cystinosis: 1) Diagnosis of was confirmed by ANY of the following: a) the presence of increased cystine concentration in leukocytes, OR b) genetic testing, OR c) demonstration of corneal cystine crystals by slit lamp examination, AND 2) the patient has experienced an intolerance to prior therapy with Cystagon (cysteamine bitartrate immediate-release). |
| **Age Restrictions** | 1 year of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PROLATE AET

## Products Affected

- Oxycodone And Acetaminophen
- Oxycodone Hydrochloride/acetaminophen SOLN 300MG/5ML; 10MG/5ML
- Oxycodone/acetaminophen TABS 300MG; 10MG, 300MG; 5MG
- Prolate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate: The patient has experienced an intolerance to two other generic acetaminophen-oxycodone combination products due to an adverse event (e.g., rash, nausea, vomiting, anaphylaxis) that is due to an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PROLENSA AET

## Products Affected

- Bromfenac Sodium SOLN 0.07%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of postoperative inflammation and reduction of ocular pain in a patient who has undergone cataract surgery: patient has experienced an intolerable adverse event to brand Prolensa caused by an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# PROMACTA

## Products Affected

- Promacta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic or persistent immune thrombocytopenia (ITP): 1) For new starts: a) Patient (pt) has had an inadequate response or is intolerant to a prior therapy such as corticosteroids or immunoglobulins AND b) Untransfused platelet (plt) count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000-50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes pt to trauma) AND c) For chronic ITP only: pt has had an inadequate response or intolerance to Doptelet (avatrombopag). 2) For continuation of therapy, plt count response to the requested drug: a) Current plt count is less than or equal to 200,000/mcL, OR b) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to a plt count sufficient to avoid clinically important bleeding. For thrombocytopenia associated with chronic hepatitis C: 1) For new starts: the requested drug is used for initiation and maintenance of interferon-based therapy. 2) For continuation of therapy: pt is receiving interferon-based therapy. For severe aplastic anemia (AA): 1) For new starts: a) Pt will use the requested drug with standard immunosuppressive therapy for first line treatment OR b) the pt had an insufficient response to immunosuppressive therapy. 2) For continuation of therapy: 1) Current plt count is 50,000-200,000/mcL, OR 2) Current plt count is less than 50,000/mcL and pt has not received appropriately titrated therapy for at least 16 weeks, OR 3) Current plt count is less than 50,000/mcL and pt is transfusion-independent, OR 4) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to achieve and maintain an appropriate target plt count. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | HCV: 6mo, ITP/AA initial: 6mo, ITP reauth: Plan Year, AA reauth: APR-Plan Year, IPR-16 wks |
| **Other Criteria** | APR: adequate platelet response (greater than 50,000/mcL), IPR: inadequate platelet response (less than 50,000/mcL). |

# PULMOZYME

## Products Affected

- Pulmozyme SOLN 2.5MG/2.5ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# PYRUKYND

## Products Affected

- Pyrukynd
- Pyrukynd Taper Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hemolytic anemia in a patient with pyruvate kinase (PK) deficiency: Diagnosis was confirmed by an enzyme assay demonstrating deficiency of PK enzyme activity or by genetic testing. For hemolytic anemia in a patient with PK deficiency (continuation of therapy): Patient achieved or maintained a positive clinical response (e.g., improvement in hemoglobin levels, reduction in blood transfusions). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 7 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# QBREXZA

## Products Affected

- Qbrexza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 9 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# QELBREE

## Products Affected

- Qelbree

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient meets all of the following: 1) the patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD), AND 2) the patient will be monitored closely for suicidal thinking or behavior, clinical worsening, and unusual changes in behavior, AND 3) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to atomoxetine OR the patient has difficulty swallowing oral capsules. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# QINLOCK

**Products Affected**

- Qinlock

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent/progressive or unresectable gastrointestinal stromal tumor (GIST) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For unresectable, recurrent/progressive, advanced, or metastatic gastrointestinal stromal tumor (GIST), the patient meets either of the following: 1) patient has received prior treatment with 3 or more kinase inhibitors, including imatinib OR 2) patient has experienced disease progression following treatment with avapritinib and dasatinib. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# QUETIAPINE XR

## Products Affected

- Quetiapine Fumarate Er
- Seroquel Xr

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Maintenance monotherapy treatment in bipolar I disorder, monotherapy treatment of generalized anxiety disorder, monotherapy treatment of major depressive disorder |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications: If the patient is 65 years of age or older AND is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, sertraline, clonazepam, escitalopram, alprazolam, zolpidem) with the requested drug, the prescriber determined that taking multiple central nervous system (CNS) active medications is medically necessary. [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls]. For treatment of schizophrenia: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine immediate-release, risperidone, ziprasidone. For acute treatment of manic or mixed episodes associated with bipolar I disorder or maintenance treatment of bipolar I disorder: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine immediate-release, risperidone, ziprasidone. For acute treatment of depressive episodes associated with bipolar I disorder: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: lurasidone, olanzapine, quetiapine immediate-release. For acute treatment of depressive episodes associated with bipolar II disorder: The patient experienced an inadequate treatment response or intolerance to generic quetiapine immediate-release. For adjunctive treatment of major depressive disorder (MDD): The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, olanzapine, quetiapine immediate-release. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# QUININE SULFATE

## Products Affected

- Qualaquin
- Quinine Sulfate CAPS 324MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Babesiosis, uncomplicated Plasmodium vivax malaria. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For babesiosis: the requested drug is used in combination with clindamycin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# QULIPTA

## Products Affected

- Qulipta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and the patient had a reduction in migraine days per month from baseline. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 3 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# QUTENZA

## Products Affected

- Qutenza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For postherpetic neuralgia (PHN) and diabetic peripheral neuropathy (DPN) of the feet: The patient has experienced an inadequate treatment response to one month of generic gabapentin or has an intolerance or contraindication to gabapentin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# QUVIVIQ

**Products Affected**

- Quviviq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For insomnia: Potential factors contributing to sleep disturbances (e.g., inappropriate sleep hygiene, sleep environment issues, treatable comorbid medical/psychiatric disorders) have been addressed or are currently being addressed. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# QUZYTTIR

**Products Affected**

- Quzyttir

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 6 months of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RADICAVA

## Products Affected

- Edaravone
- Radicava
- Radicava Ors
- Radicava Ors Starter Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For amyotrophic lateral sclerosis (ALS): 1) Diagnosis is classified as definite or probable ALS, AND 2) For new starts only: Patient has scores of at least 2 points on all 12 areas of the revised ALS Functional Rating Scale (ALSFRS-R). For continuation of therapy for ALS: There is a clinical benefit from therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RAGWITEK

## Products Affected

- Ragwitek

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy. History of eosinophilic esophagitis. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 5 to 65 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist or immunologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RAVICTI AET

## Products Affected

- Ravicti

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For urea cycle disorders (UCD): 1) Diagnosis of UCD was confirmed by enzymatic, biochemical or genetic testing AND 2) Patient has experienced an intolerance to sodium phenylbutyrate therapy, OR patient has not tried sodium phenylbutyrate because of a comorbid condition that prohibits a trial due to its sodium content (e.g., heart failure, hypertension, renal impairment, edema). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REBIF OPEN

## Products Affected

- Rebif
- Rebif Rebidose
- Rebif Rebidose Titration Pack
- Rebif Titration Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease]: Patient must have tried and failed or has a contraindication or intolerance to two of the following: brand Aubagio, Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone, brand Tecfidera, Vumerity (diroximel fumarate), Zeposia (ozanimod). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REBLOZYL

## Products Affected

- Reblozyl

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For anemia with beta thalassemia or anemia in myelodysplastic syndromes or myelodysplastic/myeloproliferative neoplasm, patient meets the following: For new starts, the patient has a diagnosis of anemia evidenced by a pretreatment or pretransfusion hemoglobin level less than or equal to 11 grams per deciliter (g/dL). For continuation of therapy, patient meets all of the following: 1) patient has a pre-dose hemoglobin level less than or equal to 11 g/dL (the current or current pretransfusion hemoglobin level must be considered for dosing purposes) or the prescriber agrees to hold the dose until the hemoglobin level falls to or below 11 g/dL, 2) patient must achieve or maintain red blood cell transfusion burden reduction or they have not received three consecutive doses at the maximum dose, and 3) patient must not experience an unacceptable toxicity on the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | For beta thalassemia: 16 weeks. For myelodysplastic syndromes: 24 weeks. |
| **Other Criteria** | N/A |

# REBYOTA

## Products Affected

- Rebyota

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the prevention of recurrence of Clostridioides difficile infection (CDI): 1) The diagnosis of CDI has been confirmed by a positive stool test for C. difficile toxin or toxigenic C. difficile, AND 2) The requested drug will be administered 24 to 72 hours after the last dose of antibiotics used for the treatment of recurrent CDI. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# RECARBRIO

## Products Affected

- Recarbrio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility OR 2) local epidemiology and susceptibility patterns. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist. |
| **Coverage Duration** | 14 days |
| **Other Criteria** | N/A |

# RECORLEV

## Products Affected

- Recorlev

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REGRANEX

## Products Affected

- Regranex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 20 weeks |
| **Other Criteria** | N/A |

# RELEUKO

## Products Affected

- Releuko

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Hematopoietic syndrome of acute radiation syndrome, mobilization of peripheral blood progenitor cells (PBPCs), neutropenia in myelodysplastic syndromes (MDS), agranulocytosis, neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia, neutropenia related to renal transplantation |
| **Exclusion Criteria** | Use of the requested product within 24 hours prior to or following chemotherapy. |
| **Required Medical Information** | For prophylaxis or treatment of myelosuppressive chemotherapy-induced febrile neutropenia (FN), patient must meet all of the following: 1) Patient has a solid tumor or non-myeloid cancer AND 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# RELISTOR INJ

## Products Affected

- Relistor INJ

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of opioid-induced constipation in a patient with chronic non-cancer pain, including chronic pain related to prior cancer or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation: 1) the patient is unable to tolerate oral medications OR 2) the patient meets one of the following criteria A) experienced an inadequate treatment response or intolerance to an oral drug indicated for opioid-induced constipation in a patient with chronic non-cancer pain (e.g., Movantik) OR B) the patient has a contraindication that would prohibit a trial of an oral drug indicated for opioid-induced constipation in a patient with chronic non-cancer pain (e.g., Movantik). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 4 months |
| **Other Criteria** | N/A |

# RELISTOR TAB

## Products Affected

- Relistor TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 4 months |
| **Other Criteria** | N/A |

# RELTONE

## Products Affected

- Reltone
- Ursodiol CAPS 200MG, 400MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For a patient with radiolucent, noncalcified gallbladder stones less than 20 millimeters in greatest diameter in whom elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery: the dosage cannot be accommodated with generic ursodiol 300 milligram (mg) capsules. For the prevention of gallstone formation in an obese patient experiencing rapid weight loss: the patient has experienced an intolerance to generic ursodiol 300 mg capsules due to an adverse event (e.g., rash, nausea, vomiting, anaphylaxis) caused by an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RELYVRIO

## Products Affected

- Relyvrio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For amyotrophic lateral sclerosis (ALS): 1) Patient has a diagnosis of definite or probable ALS AND 2) For continuation of therapy: There is a clinical benefit from therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REMICADE

## Products Affected

- Infliximab
- Remicade

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Behcet's syndrome, hidradenitis suppurativa, juvenile idiopathic arthritis, pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, uveitis. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) Pt meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) or leflunomide OR b) intolerance or CI to MTX AND leflunomide, AND 2) Pt meets ANY of the following: a) inadequate response, intolerance or CI to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at time of diagnosis, AND 2) Pt meets ANY of the following: a) pt has experienced inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with MTX, cyclosporine, or acitretin, OR b) pharmacologic treatment with MTX, cyclosporine, or acitretin is contraindicated, OR c) pt has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | For hidradenitis suppurativa (new starts only): Pt has severe, refractory disease. For uveitis (new starts only): Inadequate response or intolerance or has a CI to a trial of immunosuppressive therapy for uveitis. For FDA-approved indications and off-label uses that overlap: The patient had an intolerable adverse event to Renflexis and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. |

# RENFLEXIS

## Products Affected

- Renflexis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Behcet's syndrome, hidradenitis suppurativa, juvenile idiopathic arthritis, pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, uveitis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) Pt meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) or leflunomide OR b) intolerance or CI to MTX AND leflunomide, AND 2) pt meets ANY of the following: a) inadequate response, intolerance or CI to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis (new starts only): an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at time of diagnosis, AND 2) Pt meets ANY of the following: a) pt has experienced inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with MTX, cyclosporine, or acitretin, OR b) pharmacologic treatment with MTX, cyclosporine, or acitretin is contraindicated, OR c) pt has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | For hidradenitis suppurativa (new starts only): pt has severe, refractory disease. For uveitis (new starts only): Inadequate response or intolerance or has a CI to a trial of immunosuppressive therapy for uveitis. |

# REPATHA

## Products Affected

- Repatha
- Repatha Pushtronex System
- Repatha Sureclick

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RETEVMO

## Products Affected

- Retevmo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent rearranged during transfection (RET)-rearrangement positive non-small cell lung cancer, Langerhans Cell Histiocytosis with a RET gene fusion, symptomatic or relapsed/refractory Erdheim-Chester Disease with a RET gene fusion, symptomatic or relapsed/refractory Rosai-Dorfman Disease with a RET gene fusion, RET-fusion positive recurrent or persistent thyroid carcinoma (papillary carcinoma, follicular carcinoma, and Hurthle cell carcinoma), RET-fusion positive anaplastic thyroid carcinoma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For non-small cell lung cancer, patient must meet all of the following: 1) The disease is recurrent, advanced or metastatic, and 2) Tumor is RET fusion-positive or RET rearrangement-positive. |
| **Age Restrictions** | Medullary thyroid cancer and thyroid cancer: 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REVCOVI

## Products Affected

- Revcovi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REVLIMID

## Products Affected

- Lenalidomide
- Revlimid

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Systemic light chain amyloidosis, classical Hodgkin lymphoma, myelodysplastic syndrome without the 5q deletion cytogenetic abnormality, myelofibrosis-associated anemia, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome, myeloproliferative neoplasms, Kaposi Sarcoma, Langerhans cell histiocytosis, peripheral T-Cell lymphomas not otherwise specified, angioimmunoblastic T-cell lymphoma (AITL), enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma, adult T-cell leukemia/lymphoma, hepatosplenic T-cell lymphoma, primary central nervous system (CNS) lymphoma, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, monomorphic post-transplant lymphoproliferative disorder, diffuse large B-cell lymphoma, multicentric Castleman's disease, high-grade B-cell lymphomas, histologic transformation of indolent lymphoma to diffuse large B-cell lymphoma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For myelodysplastic syndrome (MDS): patient has lower risk MDS with symptomatic anemia per the Revised International Prognostic Scoring System (IPSS-R), International Prognostic Scoring System (IPSS), or World Health organization (WHO) classification-based Prognostic Scoring System (WPSS). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REYVOW

## Products Affected

- Reyvow

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute migraine: 1) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to at least one triptan 5-HT1 receptor agonist AND 2) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to Nurtec ODT (rimegepant) or Ubrelvy (ubrogepant). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REZDIFFRA

## Products Affected

- Rezdiffra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For noncirrhotic nonalcoholic steatohepatitis (NASH) (initial): patient has moderate to advanced liver fibrosis (consistent with Stages F2 to F3) at baseline, which was confirmed by liver biopsy or magnetic resonance elastography (MRE). For NASH (continuation): The patient demonstrates a beneficial response to therapy (for example, improvement in liver function such as reduction in alanine aminotransferase (ALT), reduction of liver fat content by imaging such as magnetic resonance imaging-protein density fat fraction (MRI-PDFF) or FibroScan controlled attenuation parameter (CAP)). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist or hepatologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REZLIDHIA

## Products Affected

- Rezlidhia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REZUROCK

## Products Affected

- Rezurock

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# REZZAYO

## Products Affected

- Rezzayo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | 6 weeks |
| **Other Criteria** | N/A |

# RIABNI

## Products Affected

- Riabni

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, extranodal marginal zone lymphoma), Burkitt lymphoma, primary cutaneous B-cell lymphoma, high-grade B-cell lymphoma, histological transformation from indolent lymphomas to diffuse large B-cell lymphoma, histological transformation from chronic lymphocytic leukemia (CLL)/SLL to diffuse large B-cell lymphoma, Castleman disease, human immunodeficiency virus (HIV)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD), B-cell lymphoblastic lymphoma], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, immune checkpoint inhibitor-related toxicities, pemphigus vulgaris, Pediatric aggressive mature B-cell lymphomas, Rosai-Dorfman disease, and Pediatric mature B-cell acute leukemia (B-AL). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Hematologic malignancies must be CD20-positive. For multiple sclerosis: 1) patient has a diagnosis of relapsing remitting multiple sclerosis, AND 2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment. |

| | |
|---|---|
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year |
| **Other Criteria** | The patient had an intolerable adverse event to Truxima and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. |

# RINVOQ

## Products Affected

- Rinvoq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For active psoriatic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For moderately to severely active ulcerative colitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Humira [adalimumab], Idacio [adalimumab-aacf]). For moderately to severely active Crohn's disease (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Humira [adalimumab], Idacio [adalimumab-aacf]). For atopic dermatitis (new starts only): 1) patient has refractory, moderate to severe disease, AND 2) patient has had an inadequate response to treatment with other systemic drug products, including biologics, or use of these therapies are inadvisable. For atopic dermatitis (continuation of therapy): the patient achieved or maintained positive clinical response. For active ankylosing spondylitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor. |
| **Age Restrictions** | Atopic dermatitis: 12 years of age or older |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Atopic dermatitis (initial): 4 months, All others: Plan Year |
| **Other Criteria** | For active polyarticular juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel (etanercept), Humira [adalimumab], Idacio [adalimumab-aacf]). |

# RINVOQ LQ

## Products Affected

- Rinvoq Lq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For active psoriatic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For moderately to severely active ulcerative colitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Humira [adalimumab], Idacio [adalimumab-aacf]). For moderately to severely active Crohn's disease (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Humira [adalimumab], Idacio [adalimumab-aacf]). For atopic dermatitis (new starts only): 1) patient has refractory, moderate to severe disease, AND 2) patient has had an inadequate response to treatment with other systemic drug products, including biologics, or use of these therapies are inadvisable. For atopic dermatitis (continuation of therapy): the patient achieved or maintained positive clinical response. For active ankylosing spondylitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor. |
| **Age Restrictions** | Atopic dermatitis: 12 years of age or older |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Atopic dermatitis (initial): 4 months, All others: Plan Year |
| **Other Criteria** | For active polyarticular juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel (etanercept), Humira [adalimumab], Idacio [adalimumab-aacf]). |

# RITUXAN

## Products Affected

- Rituxan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, extranodal marginal zone lymphoma), primary cutaneous B-cell lymphoma, high-grade B-cell lymphoma, histological transformation from indolent lymphomas to diffuse large B-cell lymphoma, histological transformation from chronic lymphocytic leukemia (CLL)/SLL to diffuse large B-cell lymphoma, Castleman disease, human immunodeficiency virus (HIV)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD), B-cell lymphoblastic lymphoma], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, immune checkpoint inhibitor-related toxicities, pediatric aggressive mature B-cell lymphomas, and Rosai-Dorfman disease. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Hematologic malignancies must be CD20-positive. For multiple sclerosis: 1) patient has a diagnosis of relapsing remitting multiple sclerosis, AND 2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment. |

| | |
|---|---|
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year |
| **Other Criteria** | The patient had an intolerable adverse event to Truxima and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. |

# RITUXAN HYCELA

## Products Affected

- Rituxan Hycela

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Castleman disease (CD), high-grade B-cell lymphoma, histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, marginal zone lymphomas (nodal marginal zone lymphoma, extranodal marginal zone lymphoma, and splenic marginal zone lymphoma), mantle cell lymphoma, post-transplant lymphoproliferative disorder (PTLD), primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas), hairy cell leukemia, small lymphocytic lymphoma (SLL), Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Malignancies must be CD20 positive. Patient must receive at least one full dose of a rituximab product by intravenous infusion without experiencing severe adverse reactions. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RIVFLOZA

## Products Affected

- Rivfloza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary hyperoxaluria type 1 (PH1): diagnosis has been confirmed by a molecular genetic test showing a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene or liver enzyme analysis demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity. For PH1 (continuation): the patient has experienced decreased or normalized levels of urinary oxalate since initiating therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ROLVEDON

## Products Affected

- Rolvedon

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For prophylaxis of myelosuppressive chemotherapy-induced febrile neutropenia, the patient must meet all of the following: 1) Patient has a solid tumor or non-myeloid cancer AND 2) Patient is currently receiving or will be receiving treatment with myelosuppressive anti-cancer therapy AND 3) The requested drug will be administered at least 24 hours after chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# ROZLYTREK

## Products Affected

- Rozlytrek

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent ROS1-positive non-small cell lung cancer (NSCLC), Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, the disease is without a known acquired resistance mutation. For ROS1-positive non-small cell lung cancer, the patient has recurrent, advanced, or metastatic disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RUBRACA

## Products Affected

- Rubraca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Uterine leiomyosarcoma, pancreatic adenocarcinoma, advanced (stage II-IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For metastatic castration-resistant prostate cancer with a deleterious breast cancer susceptibility gene (BRCA) mutation (germline and/or somatic): 1) patient has been treated with androgen receptor-directed therapy, AND 2) patient has been treated with a taxane-based chemotherapy or the patient is not fit for chemotherapy, AND 3) the requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. For maintenance treatment of BRCA mutated epithelial ovarian, fallopian tube, primary peritoneal cancer: 1) the patient has advanced (stage II-IV) disease and is in complete or partial response to primary therapy, OR 2) the patient has recurrent disease and is in complete or partial response to platinum-based chemotherapy. For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy, AND 2) the patient has BRCA-altered disease. For pancreatic adenocarcinoma: 1) the patient has metastatic disease, AND 2) the patient has somatic or germline BRCA or PALB-2 mutations. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RUCONEST

## Products Affected

- Ruconest

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute angioedema attacks due to hereditary angioedema (HAE): Patient meets either of the following: 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the 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 b) the 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. |
| **Age Restrictions** | 13 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an Immunologist, allergist, or rheumatologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RUXIENCE

## Products Affected

- Ruxience

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, extranodal marginal zone lymphoma), Burkitt lymphoma, primary cutaneous B-cell lymphoma, high-grade B-cell lymphoma, histological transformation from indolent lymphomas to diffuse large B-cell lymphoma, histological transformation from chronic lymphocytic leukemia (CLL)/SLL to diffuse large B-cell lymphoma, Castleman disease, human immunodeficiency virus(HIV)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD), B-cell lymphoblastic lymphoma], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, immune checkpoint inhibitor-related toxicities, pemphigus vulgaris, pediatric aggressive mature B-cell lymphomas, Rosai-Dorfman disease, and pediatric mature B-cell acute leukemia. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Hematologic malignancies must be CD20-positive. For multiple sclerosis: 1) patient has a diagnosis of relapsing remitting multiple sclerosis, AND 2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment. |

| | |
|---|---|
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year |
| **Other Criteria** | The patient had an intolerable adverse event to Truxima and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. |

# RYBELSUS

## Products Affected

- Rybelsus

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | The Prior Authorization only applies to patients whose claim is not submitted with an ICD-10 code indicating a diagnosis of type 2 diabetes mellitus OR to patients who do not have a history of an antidiabetic drug (EXCLUDING glucagon-like peptide receptor agonists [GLP-1 RAs] and combination glucose-dependent insulinotropic polypeptide [GIP] and GLP-1 RAs). |

# RYBREVANT

## Products Affected

- Rybrevant

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) mutation-positive disease |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For non-small cell lung cancer: 1) the disease is recurrent, advanced, or metastatic, AND 2) the patient has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RYDAPT

## Products Affected

- Rydapt

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Relapsed or refractory acute myeloid leukemia (AML), myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or FLT3 rearrangements, post-induction therapy for AML, re-induction in residual disease for AML |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute myeloid leukemia (AML): AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and Fibroblast growth factor receptor type 1 (FGFR1) or FLT3 rearrangements: the disease is in chronic or blast phase. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RYLAZE

## Products Affected

- Rylaze

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Acute myeloid leukemia (AML), nasal type extranodal natural killer (NK)/T-cell lymphoma (ENKTL) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RYPLAZIM

## Products Affected

- Ryplazim

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RYSTIGGO

## Products Affected

- Rystiggo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# RYTELO

## Products Affected

- Rytelo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For new starts, patient meets all of the following: 1) patient has not responded to, has lost response to, or is ineligible for erythropoiesis-stimulating agents (ESAs), AND 2) patient has been receiving regular red blood cell transfusions as defined by greater than or equal to 4 units per 8 weeks. For continuation of therapy, patient meets all of the following: 1) patient must achieve or maintain red blood cell transfusion burden reduction, AND 2) patient must not experience an unacceptable toxicity on the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 24 weeks |
| **Other Criteria** | N/A |

# SAMSCA

## Products Affected

- Samsca
- Tolvaptan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Therapy with the requested drug was initiated (or re-initiated) in the hospital. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 30 days |
| **Other Criteria** | N/A |

# SANDOSTATIN LAR

## Products Affected

- Sandostatin Lar Depot

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Tumor control of thymomas and thymic carcinomas, tumor control of neuroendocrine tumors (NETs) of the pancreas, gastrointestinal tract, lung, thymus, unresected primary gastrinoma, well-differentiated grade 3 NETs, pheochromocytoma/paraganglioma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. The requested drug will be used for tumor control for any of the following: 1) Neuroendocrine tumor (NET) of the gastrointestinal tract or pancreas in patients with recurrent, locoregional advanced disease and/or distant metastatic disease, OR 2) NET of the thymus or lung in patients with locoregional unresectable disease and/or distant metastatic disease, OR 3) Unresected primary gastrinoma, OR 4) Well-differentiated grade 3 unresectable locally advanced or metastatic NET with favorable biology (e.g., relatively low Ki-67 [less than 55%] and positive somatostatin receptor [SSTR]-based positron emission tomography [PET] imaging), OR 5) Thymomas or thymic carcinomas when the following criteria are met: a) Locally advanced or metastatic disease OR b) Postoperatively following tumor resection, OR 6) Pheochromocytomas or paragangliomas when the following criteria is met: a) Locally unresectable OR b) Distant metastatic disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | N/A |

# SAPHNELO

## Products Affected

- Saphnelo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will not be used in combination with other biologic therapies. For moderate to severe systemic lupus erythematosus (SLE): 1) Patient meets either of the following criteria: a) patient is receiving a stable standard therapy regimen (e.g., corticosteroid, antimalarial, or NSAIDs), OR b) patient has experienced an intolerance, or has a contraindication to standard therapy regimen for SLE, AND 2) For new starts: patient does not have severe active lupus nephritis or severe active central nervous system lupus. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SAPROPTERIN

## Products Affected

- Javygtor
- Kuvan
- Sapropterin Dihydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For phenylketonuria (PKU): For patients who have not yet received a therapeutic trial of the requested drug, the patient's pretreatment (including before dietary management) phenylalanine level is greater than 6 mg/dL (360 micromol/L). For patients who completed a therapeutic trial of the requested drug, the patient must have experienced improvement (e.g., reduction in blood phenylalanine levels, improvement in neuropsychiatric symptoms). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 2 months, All others: Plan Year |
| **Other Criteria** | N/A |

# SARCLISA

## Products Affected

- Sarclisa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SAVELLA

## Products Affected

- Savella
- Savella Titration Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to duloxetine or pregabalin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SCEMBLIX

## Products Affected

- Scemblix

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic myeloid leukemia (CML) in the chronic phase: 1) the diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene AND 2) the patient meets either of the following: A) the patient has previously been treated with 2 or more tyrosine kinase inhibitors (TKIs) AND at least one of those was imatinib or dasatinib, OR B) the patient is positive for the T315I mutation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SEGLENTIS

## Products Affected

- Seglentis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the management of acute pain: 1) Patient had an inadequate response to a two-pill regimen of tramadol and celecoxib OR 2) Patient has experienced an intolerance, or has a contraindication caused by an inactive ingredient in generic tramadol or generic celecoxib. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SEROSTIM

## Products Affected

- Serostim INJ 4MG, 5MG, 6MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of human immunodeficiency virus (HIV) patients with wasting or cachexia: The requested medication is used in combination with antiretroviral therapy. Patient has had a suboptimal response to at least one other therapy for wasting or cachexia (e.g., megestrol, dronabinol, cyproheptadine, or testosterone therapy if hypogonadal) or patient has a contraindication or intolerance to alternative therapies. For continuation of therapy, patient must have demonstrated a response to therapy with the requested medication (i.e., body mass index [BMI] has increased or stabilized). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 weeks |
| **Other Criteria** | N/A |

# SEYSARA

## Products Affected

- Seysara

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For inflammatory lesions of non-nodular moderate to severe acne vulgaris: 1) The patient has experienced an inadequate treatment response to doxycycline (regular or extended-release) or minocycline (regular or extended-release) OR 2) The patient has experienced an intolerance to doxycycline (regular or extended-release) or minocycline (regular or extended-release). |
| **Age Restrictions** | 9 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SIGNIFOR

## Products Affected

- Signifor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SIGNIFOR LAR

## Products Affected

- Signifor Lar

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, AND 2) Patient had an inadequate or partial response to surgery OR there is a clinical reason for why the patient has not had surgery. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SIKLOS

## Products Affected

- Siklos

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SILDENAFIL

## Products Affected

- Revatio SUSR
- Revatio TABS
- Sildenafil Citrate SUSR
- Sildenafil Citrate TABS 20MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) If the request is for an adult, pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SILDENAFIL INJ

## Products Affected

- Revatio INJ
- Sildenafil INJ

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) If the request is for an adult, pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | Patient was previously receiving oral Revatio or sildenafil but is now temporarily unable to take oral medications. |

# SILIQ

## Products Affected

- Siliq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SIMPONI

## Products Affected

- Simponi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) requested drug will be used in combination with methotrexate (MTX) unless MTX is contraindicated or was not tolerated AND 2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active ankylosing spondylitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For moderately to severely active ulcerative colitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active psoriatic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SIMPONI ARIA

## Products Affected

- Simponi Aria

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) requested drug will be used in combination with methotrexate (MTX) or MTX is contraindicated or was not tolerated AND 2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active ankylosing spondylitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For an adult with active psoriatic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active polyarticular juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SIRTURO

## Products Affected

- Sirturo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SKYCLARYS

## Products Affected

- Skyclarys

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Friedreich's ataxia (FRDA): 1) The patient has a confirmed genetic mutation in the frataxin (FXN) gene, AND 2) The patient is exhibiting clinical manifestations of the disease (e.g., muscle weakness, decline in coordination, frequent falling). For FRDA continuation of therapy: The patient has experienced a beneficial response to therapy (e.g., slowing of clinical decline). |
| **Age Restrictions** | 16 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a physician who specializes in Friedreich's ataxia or a neurologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SKYRIZI

## Products Affected

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML, 600MG/10ML
- Skyrizi Pen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe plaque psoriasis (new starts only): at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SKYTROFA AET

## Products Affected

- Skytrofa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Pediatric patients with closed epiphyses |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Genotropin. If using target medication for a medically accepted indication not shared by Genotropin, then no trial of Genotropin is required for that target medication. Pediatric growth hormone deficiency (GHD), initial: A) Patient (pt) 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, OR B) pt was diagnosed with GHD as a neonate. Pediatric GHD, continuation of therapy: Patient is experiencing improvement. |
| **Age Restrictions** | 1 year of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SOFOSBUVIR AND VELPATASVIR AET

**Products Affected**

- Sofosbuvir/velpatasvir

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. The patient must have a contraindication or intolerance to 2 of the following, if appropriate, based on current AASLD/IDSA guidance: Epclusa (velpatasvir and sofosbuvir), Harvoni (ledipasvir and sofosbuvir), Mavyret (glecaprevir and pibrentasvir), Vosevi (sofosbuvir, velpatasvir, and voxilaprevir) AND the criteria will be applied consistent with current AASLD/IDSA guidance. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD-IDSA guidance |
| **Other Criteria** | N/A |

# SOGROYA AET

## Products Affected

- Sogroya

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Pediatric growth hormone deficiency (GHD): Pediatric patients with closed epiphyses |
| **Required Medical Information** | For all indications: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Genotropin. If using target medication for a medically accepted indication not shared by Genotropin, then no trial of Genotropin is required for that target medication. For adult GHD: Patient meets ANY of the following: 1) failed 2 pre-treatment growth hormone (GH) stimulation tests OR 2) pre-treatment insulin-like growth factor-1 (IGF-1) more than 2 standard deviations (SD) below mean AND failed 1 pre-treatment 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 a patient with a body mass index [BMI] 25-30 kg/m2 and high pretest probability of growth hormone deficiency [GHD] [e.g., acquired structural abnormalities] or BMI less than 25 kg/m2, OR d) GST [peak GH level less than or equal to 1 ng/ml] in a patient with BMI 25-30 kg/m2 and low pretest probability of GHD or BMI greater than 30kg/m2), 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-treatment IGF-1 more than 2 SD below mean, OR 4) genetic or structural hypothalamic-pituitary defect, OR 5) childhood-onset GHD with congenital (genetic or structural) abnormality of the hypothalamus/pituitary/CNS. |
| **Age Restrictions** | Pediatric growth hormone deficiency (GHD): 2.5 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | For pediatric growth hormone deficiency (GHD): A) Patient (pt) has pre-treatment (pre-tx) 1-year height (ht) velocity more than 2 standard deviations (SD) below mean OR a pre-tx ht more than 2 SD below mean and 1-year ht velocity more than 1 SD below mean, AND pt meets any of the following: 1) failed 2 pre-tx growth hormone (GH) stimulation tests (peak below 10 ng/mL), 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, OR B) Pt was diagnosed with GHD as a neonate. |

# SOHONOS

## Products Affected

- Sohonos

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For reduction in volume of new heterotopic ossification in fibrodysplasia ossificans progressiva (FOP): The patient has a confirmed genetic mutation in the activin A receptor type I (ACVR1) gene. |
| **Age Restrictions** | 8 years of age or older if female and 10 years of age or older if male |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SOLIRIS

## Products Affected

- Soliris

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For paroxysmal nocturnal hemoglobinuria (PNH) (initial): 1) the diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by either: a) at least 5% PNH cells or b) at least 51% of GPI-AP deficient polymorphonuclear (PMN) cells AND 2) flow cytometry is used to demonstrate GPI-AP deficiency. For PNH (continuation): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) the patient (pt) has demonstrated a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels). For atypical hemolytic uremic syndrome (aHUS) (initial): the disease is not caused by Shiga toxin-producing Escherichia coli. For aHUS (continuation): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) the pt has demonstrated a positive response to therapy (e.g., normalization of lactate dehydrogenase (LDH) levels, platelet counts). For generalized myasthenia gravis (continuation): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) the pt has demonstrated a positive response to therapy (e.g., improvement in MG-ADL score). For neuromyelitis optica spectrum disorder (continuation): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) the pt has demonstrated a positive response to therapy (e.g., reduction in number of relapses). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |

| | |
|---|---|
| **Other Criteria** | N/A |

# SOMATULINE DEPOT

## Products Affected

- Lanreotide Acetate
- Somatuline Depot

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Tumor control of neuroendocrine tumors (NETs) of the lung, thymus or unresected primary gastrinoma, well-differentiated grade 3 neuroendocrine tumors not of gastroenteropancreatic origin, pheochromocytoma/paraganglioma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. For tumor control of neuroendocrine tumors (NETs) of the thymus or lung: Patient has locoregional unresectable, recurrent, and/or distant metastatic disease. For tumor control of well-differentiated grade 3 unresectable locally advanced or metastatic NETs (not of gastroenteropancreatic origin): Patient has favorable biology (e.g., relatively low Ki-67 [less than 55%] and positive somatostatin receptor [SSTR]-based positron emission tomography [PET] imaging). For tumor control of pheochromocytomas or paragangliomas: Patient has locally unresectable or distant metastatic disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SOMAVERT

## Products Affected

- Somavert

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SOTYKTU

## Products Affected

- Sotyktu

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe plaque psoriasis (new starts only): 1) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SOVALDI AET

**Products Affected**

- Sovaldi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For HCV: Infection confirmed by presence of HCV RNA in serum prior to starting treatment. The patient must have a contraindication or intolerance to 2 of the following, if appropriate, based on current AASLD/IDSA guidance: Epclusa (velpatasvir and sofosbuvir), Harvoni (ledipasvir and sofosbuvir), Mavyret (glecaprevir and pibrentasvir), Vosevi (sofosbuvir, velpatasvir, and voxilaprevir) AND the criteria will be applied consistent with current AASLD/IDSA guidance. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. For patients with genotype 1, 2, 3, or 4 infection and hepatocellular carcinoma awaiting liver transplantation: must meet MILAN criteria. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD-IDSA guidance. |
| **Other Criteria** | MILAN criteria defined as: 1) tumor size 5 cm or less in diameter in patients with single hepatocellular carcinoma OR 3 tumor nodules or less, each 3 cm or less in diameter in patients with multiple tumors, and 2) no extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor. |

# SPEVIGO

## Products Affected

- Spevigo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SPRIX

## Products Affected

- Ketorolac Tromethamine NASAL SOLN 15.75MG/SPRAY
- Sprix

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs). In the setting of coronary artery bypass graft (CABG) surgery. Patients with active peptic ulcer disease or recent gastrointestinal bleeding or perforation. Patients with advanced renal disease or at risk for renal failure due to volume depletion. Use in labor and delivery. Use in patients with suspected or confirmed cerebrovascular bleeding, hemorrhagic diathesis, incomplete hemostasis, or those for whom hemostasis is critical. Concomitant use with probenecid or pentoxifylline. |
| **Required Medical Information** | For short term management of moderate to moderately severe pain: The patient is unable to tolerate oral medications. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 days |
| **Other Criteria** | N/A |

# SPRYCEL

## Products Affected

- Dasatinib
- Sprycel

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Gastrointestinal stromal tumor (GIST), metastatic chondrosarcoma, recurrent chordoma, T-cell acute lymphoblastic leukemia (ALL), and Philadelphia (Ph)-like B-ALL, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia (Ph) chromosome or BCR-ABL gene, and 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L. For acute lymphoblastic leukemia (ALL), the patient has a diagnosis of one of the following: 1) Philadelphia chromosome positive ALL, including patients who have received a hematopoietic stem cell transplant: diagnosis that has been confirmed by detection of the Ph chromosome or BCR-ABL gene, and if patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L, OR 2) Ph-like B-ALL with ABL-class kinase fusion, OR 3) relapsed or refractory T-cell ALL with ABL-class kinase fusion. For GIST, 1) the patient meets all of the following: A) the disease is unresectable, recurrent/progressive, or metastatic, B) the patient has received prior therapy with imatinib or avapritinib AND C) patients is positive for PDGFRA exon 18 mutations, OR 2) the requested drug is being used for palliation of symptoms. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | N/A |

# STELARA

## Products Affected

- Stelara

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe plaque psoriasis (new starts): At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# STIMUFEND

## Products Affected

- Stimufend

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Stem cell transplantation-related indications |
| **Exclusion Criteria** | Use of the requested product less than 24 hours before or after chemotherapy. |
| **Required Medical Information** | For prophylaxis of myelosuppressive chemotherapy-induced febrile neutropenia: the patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, and 2) Patient is currently receiving or will be receiving treatment with myelosuppressive anti-cancer therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# STIVARGA

## Products Affected

- Stivarga

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Progressive gastrointestinal stromal tumors (GIST), osteosarcoma, glioblastoma, angiosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma, rhabdomyosarcoma, soft tissue sarcomas of the extremities, body wall, head and neck. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For gastrointestinal stromal tumors: The disease is progressive, locally advanced, unresectable, or metastatic. For colorectal cancer: The disease is advanced or metastatic. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# STRENSIQ

**Products Affected**

- Strensiq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of perinatal/infantile- and juvenile-onset hypophosphatasia: 1) The patient has clinical signs and/or symptoms of hypophosphatasia (e.g., generalized hypomineralization with rachitic features, chest deformities and rib fractures, respiratory problems, hypercalcemia, failure to thrive, bone/joint pain, seizures) AND 2) The onset of the disease was perinatal/infantile or juvenile AND 3) The diagnosis was confirmed by the presence of mutation(s) in the ALPL gene as detected by ALPL molecular genetic testing OR the diagnosis was supported by ALL of the following: a) radiographic imaging demonstrating skeletal abnormalities (e.g., infantile rickets, alveolar bone loss, focal bony defects of the metaphyses, metatarsal stress fractures), b) low serum alkaline phosphatase (ALP) level as defined by the gender- and age-specific reference range of the laboratory performing the test and c) elevated tissue-nonspecific alkaline phosphatase (TNALP) substrate level (i.e., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi] level). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SUBLOCADE

## Products Affected

- Sublocade

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Prescribed only for the treatment of pain |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SUNOSI

## Products Affected

- Sunosi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For excessive daytime sleepiness associated with narcolepsy, initial request: 1) The diagnosis has been confirmed by sleep lab evaluation, AND 2) The patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drugs (e.g., armodafinil, modafinil). For excessive daytime sleepiness associated with obstructive sleep apnea (OSA), initial request: 1) The diagnosis has been confirmed by polysomnography, AND 2) The patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drugs (e.g., armodafinil, modafinil). If the request is for a continuation of therapy, then the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in daytime sleepiness with obstructive sleep apnea (OSA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a sleep disorder specialist or neurologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SUSVIMO

## Products Affected

- Susvimo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# SUTENT

## Products Affected

- Sunitinib Malate
- Sutent

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Thyroid carcinoma (follicular, medullary, papillary, and Hurthle cell), soft tissue sarcoma (angiosarcoma, solitary fibrous tumor, and alveolar soft part sarcoma subtypes), recurrent chordoma, thymic carcinoma, lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia, pheochromocytoma, paraganglioma, gastrointestinal stromal tumor (GIST) (unresectable, recurrent/progressive, or metastatic disease after progression on approved therapies, unresectable succinate dehydrogenase (SDH)-deficient GISTs and use for palliation of symptoms if previously tolerated and effective). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For renal cell carcinoma (RCC): the patient meets either of the following: 1) the disease is relapsed, advanced, or stage IV OR 2) the requested drug is being used as adjuvant treatment for patients that are at high risk of recurrent RCC following nephrectomy. For gastrointestinal stromal tumor (GIST): the patient meets one of the following: 1) the requested drug will be used after disease progression on or intolerance to imatinib, 2) the disease is unresectable, recurrent/progressive, or metastatic AND the patient has failed on an FDA-approved therapy (e.g., imatinib, sunitinib, regorafenib, ripretinib), 3) the requested drug will be used for unresectable succinate dehydrogenase (SDH)-deficient GIST, OR 4) the requested drug will be used for the palliation of symptoms if previously tolerated and effective. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia: 1) the disease has a FLT3 rearrangement AND 2) the disease is in chronic or blast phase. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | N/A |

# SYFOVRE

## Products Affected

- Syfovre

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# SYLVANT

## Products Affected

- Sylvant

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Relapsed or refractory unicentric Castleman's disease in patients who are human immunodeficiency virus negative and human herpesvirus-8 negative |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SYMDEKO

## Products Affected

- Symdeko

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cystic fibrosis: The requested medication will not be used in combination with other medications containing ivacaftor. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SYMLIN

## Products Affected

- Symlinpen 120
- Symlinpen 60

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SYMPAZAN

## Products Affected

- Sympazan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Seizures associated with Dravet syndrome |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Seizures associated with Lennox-Gastaut syndrome (LGS): 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# SYNERA AET

## Products Affected

- Synera

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response to a one month trial of generic topical lidocaine/prilocaine, or has an intolerance or contraindication to generic topical lidocaine/prilocaine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# TABRECTA

## Products Affected

- Tabrecta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent non-small cell lung cancer (NSCLC). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For recurrent, advanced, or metastatic NSCLC: Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TADALAFIL (PAH)

## Products Affected

- Adcirca
- Alyq
- Tadalafil TABS 20MG
- Tadliq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TAFINLAR

## Products Affected

- Tafinlar

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Thyroid carcinoma (papillary carcinoma, follicular carcinoma, and Hurthle cell carcinoma), central nervous system (CNS) cancer (i.e., oligodendroglioma, astrocytoma, glioblastoma), gallbladder cancer, extrahepatic cholangiocarcinoma, intrahepatic cholangiocarcinoma, Langerhans cell histiocytosis, Erdheim-Chester disease, ovarian cancer, fallopian tube cancer, and primary peritoneal cancer. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For central nervous system (CNS) cancer (i.e., glioma, oligodendroglioma, astrocytoma, glioblastoma): 1) The tumor is positive for a BRAF V600E mutation AND 2) The requested drug will be used in combination with trametinib. For melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with trametinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used as a single agent or in combination with trametinib. For papillary, follicular, and Hurthle cell thyroid carcinoma: 1) The tumor is BRAF-positive, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy. For Langerhans Cell Histiocytosis and Erdheim-Chester Disease: The disease is positive for a BRAF V600E mutation. For gallbladder cancer, extrahepatic cholangiocarcinoma, and intrahepatic cholangiocarcinoma: 1) The disease is positive for a BRAF V600E mutation, AND 2) The disease is unresectable or metastatic, AND 3) The requested drug will be used in combination with trametinib. For solid tumors: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used in combination with trametinib. For ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: 1) The disease is positive for BRAF V600E mutation, AND 2) The disease is persistent or recurrent, AND 3) The requested drug will be used in combination with trametinib. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TAGRISSO

**Products Affected**

- Tagrisso

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent non-small cell lung cancer (NSCLC), brain metastases from sensitizing EGFR mutation-positive NSCLC, leptomeningeal metastases from EGFR mutation-positive NSCLC. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For NSCLC, the requested drug is used in any of the following settings: 1) The patient meets both of the following: a) patient has metastatic, advanced, or recurrent NSCLC (including brain and/or leptomeningeal metastases from NSCLC) and b) patient has a sensitizing EGFR mutation OR 2) The patient meets both of the following: a) request is for adjuvant treatment of NSCLC following tumor resection and b) patient has EGFR mutation-positive disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TAKHZYRO

## Products Affected

- Takhzyro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the prevention of acute angioedema attacks due to hereditary angioedema (HAE): The patient meets either of the following: 1) the patient has hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has hereditary angioedema with normal C1 inhibitor confirmed by laboratory testing and either of the following: a) 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 b) 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. |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TALTZ

## Products Affected

- Taltz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab). For active ankylosing spondylitis (new starts only): the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active psoriatic arthritis (PsA) (new starts only): the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Otezla (apremilast), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active non-radiographic axial spondyloarthritis (new starts only): patient meets any of the following: 1) patient has experienced an inadequate treatment response to a non-steroidal anti-inflammatory drug (NSAID) OR 2) patient has experienced an intolerance or has a contraindication to NSAIDs. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | N/A |

# TALVEY

## Products Affected

- Talvey

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TALZENNA

## Products Affected

- Talzenna

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent germline breast cancer susceptibility gene (BRCA)-mutated breast cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TARGRETIN TOPICAL

## Products Affected

- Bexarotene GEL
- Targretin GEL

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Stage 2 or higher mycosis fungoides (MF)/Sezary syndrome (SS), chronic or smoldering adult T-cell leukemia/lymphoma (ATLL), primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TARPEYO

## Products Affected

- Tarpeyo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For patients with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression: 1) patient is on a stable dose of a maximally-tolerated renin-angiotensin system (RAS) inhibitor (e.g., angiotensin-converting enzyme [ACE] inhibitor or angiotensin-receptor blocker [ARB]) or patient has experienced an intolerance or has a contraindication to RAS inhibitors, AND 2) patient has experienced an intolerance to an oral glucocorticoid (e.g., prednisone). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 10 months |
| **Other Criteria** | N/A |

# TASCENSO

## Products Affected

- Tascenso Odt

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TASIGNA

**Products Affected**

- Tasigna

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), gastrointestinal stromal tumor (GIST), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase, pigmented villonodular synovitis/tenosynovial giant cell tumor |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant, 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, 2) patient has experienced resistance or intolerance to imatinib or dasatinib, AND 3) If patient experienced resistance to an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I, Y253H, E255K/V, and F359V/C/I mutations. For acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) if the patient has experienced resistance to an alternative tyrosine kinase inhibitor for ALL, patient is negative for T315I, Y253H, E255K/V, F359V/C/I and G250E. For gastrointestinal stromal tumor (GIST), the patients meets either of the following: 1) the disease is unresectable, recurrent/progressive, or metastatic AND the disease has progressed on at least 2 approved therapies (e.g. imatinib, sunitinib, dasatinib, regorafenib, ripretinib) OR 2) the requested drug is being prescribed for palliation of symptoms. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TAVALISSE

## Products Affected

- Tavalisse

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For chronic immune thrombocytopenia (ITP): 1) For new starts: patient meets all of the following: a) Patient has had an inadequate response or is intolerant to a prior therapy (e.g., corticosteroid, immunoglobulin, thrombopoietin receptor agonist), AND b) Untransfused platelet count at any point prior to the initiation of the requested medication is less than 30,000/mcL or 30,000 to 50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes patient to trauma). 2) For continuation of therapy, platelet count response to the requested drug must meet one of the following: a) current platelet count is less than or equal to 200,000/mcL, OR b) current platelet count is greater than 200,000/mcL and less than or equal to 400,000/mcL and dosing will be adjusted to a platelet count sufficient to avoid clinically important bleeding. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 12 weeks, Reauthorization: Plan Year |
| **Other Criteria** | N/A |

# TAVNEOS

## Products Affected

- Tavneos

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For continuation of treatment for severe anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: the patient has experienced benefit from therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TAZAROTENE

## Products Affected

- Tazarotene CREA
- Tazarotene GEL
- Tazorac

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For plaque psoriasis, the patient meets the following criteria: 1) the patient has less than or equal to 20 percent of affected body surface area (BSA), AND 2) the patient experienced an inadequate treatment response or intolerance to at least one topical corticosteroid OR has a contraindication that would prohibit a trial of topical corticosteroids. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TAZVERIK

## Products Affected

- Tazverik

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Epithelioid sarcoma: 16 years of age or older, Follicular lymphoma: 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TECENTRIQ

**Products Affected**

- Tecentriq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Single agent maintenance for extensive small cell lung cancer following combination treatment with etoposide and carboplatin, subsequent therapy for peritoneal mesothelioma, pericardial mesothelioma, and tunica vaginalis testis mesothelioma, primary carcinoma of the urethra. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary carcinoma of the urethra: 1) Patient is ineligible for cisplatin therapy and tumors express PD-L1 OR 2) Patient is ineligible for any platinum containing chemotherapy. For non-small cell lung cancer (NSCLC): 1) the patient has recurrent, advanced or metastatic disease AND the requested drug will be used as any of the following: a) first-line treatment of tumors with high PD-L1 expression (defined as PD-L1 stained greater than or equal to 50 percent of tumor cells or PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 10 percent of the tumor area) and no EGFR or ALK genomic tumor aberrations, b) used in combination with carboplatin, paclitaxel, and bevacizumab, or in combination with carboplatin and albumin-bound paclitaxel for non-squamous NSCLC, or c) the requested drug will be used as subsequent therapy or continuation maintenance therapy, OR 2) the patient has stage II to IIIA disease AND the requested drug will be used as adjuvant treatment following resection and adjuvant chemotherapy for tumors with PD-L1 expression on greater than or equal to 1 percent of tumor cells. For hepatocellular carcinoma, the requested drug will be used as initial treatment in combination with bevacizumab. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TECFIDERA

## Products Affected

- Tecfidera
- Tecfidera Starter Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TECVAYLI

## Products Affected

- Tecvayli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TEGSEDI

**Products Affected**

- Tegsedi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For polyneuropathy of hereditary transthyretin-mediated amyloidosis initial therapy, patient is positive for a mutation of the TTR gene and exhibits clinical manifestation of disease. For polyneuropathy of hereditary transthyretin-mediated amyloidosis continuation, patient demonstrates a beneficial response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TEMAZEPAM 30MG - 65

## Products Affected

- Restoril CAPS 30MG
- Temazepam CAPS 30MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For short-term treatment of insomnia: 1) The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: 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.) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | This Prior Authorization only applies to patients 65 years of age or older. |

# TEPEZZA

## Products Affected

- Tepezza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# TEPMETKO

## Products Affected

- Tepmetko

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent non-small cell lung cancer (NSCLC). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For recurrent, advanced, or metastatic NSCLC: Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TERIFLUNOMIDE

## Products Affected

- Teriflunomide

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsing MS [including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease]: Patient has experienced an intolerance to brand Aubagio due to an adverse event (e.g., rash, nausea, vomiting, anaphylaxis) caused by an inactive ingredient which is not contained in the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TESTOPEL

## Products Affected

- Testopel

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Gender Dysphoria |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. Gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TESTOSTERONE AET

## Products Affected

- Androderm PT24 2MG/24HR, 4MG/24HR
- Androgel Pump GEL 1.62%
- Natesto
- Testim
- Vogelxo
- Vogelxo Pump

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Gender Dysphoria |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. Gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy. For all indications: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to a generic testosterone gel. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TESTOSTERONE CYPIONATE INJ

**Products Affected**

- Depo-testosterone INJ 100MG/ML, 200MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Gender Dysphoria |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TESTOSTERONE ENANTHATE INJ

**Products Affected**

- Testosterone Enanthate INJ

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Gender Dysphoria |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TETRABENAZINE

## Products Affected

- Tetrabenazine
- Xenazine

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Tic disorders, tardive dyskinesia, hemiballismus, chorea not associated with Huntington's disease. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of tardive dyskinesia and treatment of chorea associated with Huntington's disease: The patient has experienced an inadequate treatment response or intolerable adverse event to deutetrabenazine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TEVIMBRA

## Products Affected

- Tevimbra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TEZSPIRE

## Products Affected

- Tezspire

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For severe asthma, initial therapy: Patient has a history of severe asthma despite current treatment with both of the following medications: 1) medium-to-high-dose inhaled corticosteroid, 2) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For severe asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# THALOMID

## Products Affected

- Thalomid

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Myelofibrosis-associated anemia, AIDS-related aphthous stomatitis, Kaposi sarcoma, chronic graft-versus-host disease, Crohn's disease, multicentric Castleman's disease, Rosai-Dorfman disease, Langerhans cell histiocytosis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TIBSOVO

**Products Affected**

- Tibsovo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Conventional (grades 1-3) or dedifferentiated chondrosarcoma. Newly-diagnosed acute myeloid leukemia (AML) if 60-74 years of age and without comorbidities. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient has disease with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation. For acute myeloid leukemia (AML): 1) patient has newly-diagnosed AML and meets one of the following: a) 75 years of age or older, b) patient has comorbidities that preclude use of intensive induction chemotherapy, or c) patient is 60 years of age or older and declines intensive induction chemotherapy, OR 2) patient is 60 years of age or older and the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug, OR 3) patient has relapsed or refractory AML. For locally advanced, unresectable, or metastatic cholangiocarcinoma: the requested drug will be used as subsequent treatment for progression on or after systemic treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TIVDAK

## Products Affected

- Tivdak

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TLANDO

## Products Affected

- Tlando

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Gender Dysphoria |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TOBI INHALER

## Products Affected

- Tobi Podhaler

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-cystic fibrosis bronchiectasis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cystic fibrosis and non-cystic fibrosis bronchiectasis: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of Pseudomonas aeruginosa infection or colonization in the airways. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TOBRAMYCIN

## Products Affected

- Bethkis
- Kitabis Pak
- Tobi
- Tobramycin NEBU

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-cystic fibrosis bronchiectasis |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cystic fibrosis and non-cystic fibrosis bronchiectasis: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of Pseudomonas aeruginosa infection or colonization in the airways. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# TOFIDENCE

## Products Affected

- Tofidence

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Castleman's disease, systemic sclerosis-associated interstitial lung disease |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active systemic juvenile idiopathic arthritis (JIA) (new starts only): 1) patient has experienced an inadequate treatment response to a nonsteroidal anti-inflammatory drug (NSAID) trial, a corticosteroid, methotrexate, or leflunomide, OR 2) inadequate treatment response or intolerance to a prior biologic DMARD. For active polyarticular juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TOLAK

## Products Affected

- Tolak

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Patients who are pregnant or may become pregnant. Patients with dihydropyrimidine dehydrogenase (DPD) enzyme deficiency. |
| **Required Medical Information** | If being used as part of a compounded product, all active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# TOLSURA

## Products Affected

- Tolsura

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# TOPICAL DOXEPIN

## Products Affected

- Doxepin Hydrochloride CREA
- Prudoxin
- Zonalon

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a topical corticosteroid or a topical calcineurin inhibitor. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# TOPICAL LIDOCAINE

## Products Affected

- Dermacinrx Lidogel
- Glydo
- Lidocaine OINT 5%
- Lidocaine Hcl PRSY
- Lidocaine Hydrochloride EXTERNAL SOLN
- Lidorex
- Pliaglis CREA

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) The requested drug is being used for topical anesthesia, AND 2) If the requested drug will be used as part of a compounded product, then all the active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# TOPICAL TRETINOIN

## Products Affected

- Altreno
- Atralin
- Avita
- Clindamycin Phosphate/tretinoin
- Retin-a CREA
- Retin-a GEL
- Retin-a Micro
- Retin-a Micro Pump
- Tretinoin CREA
- Tretinoin GEL
- Tretinoin Microsphere
- Tretinoin Microsphere Pump
- Twyneo
- Veltin
- Ziana

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TOREMIFENE

## Products Affected

- Fareston
- Toremifene Citrate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Congenital/acquired QT prolongation (long QT syndrome), uncorrected hypokalemia, or uncorrected hypomagnesemia. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TRAMADOL ORAL SOLUTION

## Products Affected

- Qdolo
- Tramadol Hydrochloride SOLN

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 1) The patient has experienced an intolerance, caused by an inactive ingredient, to one other formulary product such as tramadol tablets, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TRAZIMERA

## Products Affected

- Trazimera

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma), HER2-positive recurrent salivary gland tumor, HER2-positive unresectable or metastatic hepatobiliary carcinoma (gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma), HER2 overexpression positive locally advanced, unresectable, or recurrent gastric adenocarcinoma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For colorectal cancer (including appendiceal adenocarcinoma): 1) the disease is HER2-amplified and RAS and BRAF wild-type and 2) the requested drug is used in combination with pertuzumab, tucatinib or lapatinib and 3) the patient has not had previous treatment with a HER2 inhibitor. For hepatobiliary carcinoma: 1) the disease is HER2 positive and 2) the requested drug is used in combination with pertuzumab. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# TRELSTAR

## Products Affected

- Trelstar Mixject

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Gender dysphoria, ovarian suppression in breast cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For gender dysphoria, patient meets either of the following (1 or 2): 1) the requested drug is used to suppress puberty and the patient is at Tanner stage 2 or greater, OR 2) patient is undergoing gender transition, and the patient will receive the requested drug concomitantly with gender-affirming hormones. For breast cancer: 1) requested drug is being used for ovarian suppression in premenopausal patients and 2) the requested drug will be used in combination with endocrine therapy and 3) the disease is hormone receptor positive and 4) the disease is at a higher risk of recurrence (e.g., young age, high-grade tumor, lymph-node involvement). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TREMFYA

## Products Affected

- Tremfya

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe plaque psoriasis (new starts only): at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TREPROSTINIL INJ

## Products Affected

- Remodulin
- Treprostinil

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# TRIENTINE

## Products Affected

- Syprine
- Trientine Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TRIKAFTA

## Products Affected

- Trikafta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cystic fibrosis: The requested medication will not be used in combination with other medications containing ivacaftor. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TRIPTODUR

## Products Affected

- Triptodur

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For central precocious puberty (CPP): Patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, AND 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, AND 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients. |
| **Age Restrictions** | For CPP: Patient must be less than 12 years old if female and less than 13 years old if male |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TRODELVY

## Products Affected

- Trodelvy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For urothelial carcinoma, the requested drug will be used as subsequent therapy for any of the following: a) locally advanced or metastatic urothelial carcinoma, b) urothelial carcinoma of the bladder with muscle invasive local recurrence or persistent disease in a preserved bladder, c) urothelial carcinoma of the bladder with metastatic or local recurrence post cystectomy, d) recurrent primary carcinoma of the urethra, or e) stage II-IV urothelial carcinoma of the bladder. For breast cancer: 1) the disease is recurrent, advanced, or metastatic, AND 2) the requested drug will be used as subsequent therapy, AND 3) the patient has triple-negative, or hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TRULICITY

## Products Affected

- Trulicity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | The Prior Authorization only applies to patients whose claim is not submitted with an ICD-10 code indicating a diagnosis of type 2 diabetes mellitus OR to patients who do not have a history of an antidiabetic drug (EXCLUDING glucagon-like peptide receptor agonists [GLP-1 RAs] and combination glucose-dependent insulinotropic polypeptide [GIP] and GLP-1 RAs). |

# TRUQAP

## Products Affected

- Truqap

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TRUSELTIQ

## Products Affected

- Truseltiq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TRUXIMA

**Products Affected**

- Truxima

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, extranodal marginal zone lymphoma), Burkitt lymphoma, primary cutaneous B-cell lymphoma, high-grade B-cell lymphoma, histological transformation from indolent lymphomas to diffuse large B-cell lymphoma, histological transformation chronic lymphocytic leukemia (CLL)/SLL to diffuse large B-cell lymphoma, Castleman's disease, human immunodeficiency virus (HIV)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD), B-cell lymphoblastic lymphoma], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, immune checkpoint inhibitor-related toxicities, pemphigus vulgaris, pediatric aggressive mature B-cell lymphomas, Rosai-Dorfman disease, and pediatric mature B-cell acute leukemia. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Hematologic malignancies must be CD20-positive. For multiple sclerosis: 1) patient has a diagnosis of relapsing remitting multiple sclerosis, AND2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment. |

| | |
|---|---|
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year |
| **Other Criteria** | N/A |

# TRYVIO

## Products Affected

- Tryvio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hypertension: 1) the patient is currently taking other antihypertensive drugs (e.g., angiotensin converting enzyme inhibitor [ACEI], angiotensin II receptor blocker [ARB], beta-blocker, calcium channel blocker, diuretics) at maximally tolerated doses AND 2) for initial therapy, the patient's blood pressure is not adequately controlled with their current regimen. For continuation: the patient has demonstrated a positive response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# TUKYSA

## Products Affected

- Tukysa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For colorectal cancer (including appendiceal adenocarcinoma): 1) the patient has advanced, unresectable, or metastatic disease AND 2) the patient has human epidermal growth factor receptor 2 (HER2)-positive disease AND 3) the patient has RAS wild-type disease AND 4) the requested drug will be used in combination with trastuzumab and 5) the patient has not previously been treated with a HER2 inhibitor. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TURALIO

## Products Affected

- Turalio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Langerhans cell histiocytosis: 1) disease has colony stimulating factor 1 receptor (CSF1R) mutation. For Erdheim-Chester disease and Rosai-Dorfman disease: 1) disease has CSF1R mutation AND patient has any of the following: a) symptomatic disease OR b) relapsed/refractory disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TYENNE

**Products Affected**

- Tyenne

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Castleman's disease |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active systemic juvenile idiopathic arthritis (JIA) (new starts only): 1) patient has experienced an inadequate treatment response to a nonsteroidal anti-inflammatory drug (NSAID) trial, a corticosteroid, methotrexate, or leflunomide, OR 2) inadequate treatment response or intolerance to a prior biologic DMARD. For moderately to severely active polyarticular juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Kevzara (sarilumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TYMLOS

**Products Affected**

- Tymlos

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For postmenopausal osteoporosis: patient has ONE of the following: 1) a history of fragility fracture, OR 2) a pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment Fracture Risk Assessment Tool (FRAX) fracture probability AND patient has ANY of the following: a) indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR b) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy, OR c) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For osteoporosis in men: patient has ONE of the following: 1) a history of osteoporotic vertebral or hip fracture, OR 2) a pre-tx T-score of less than or equal to -2.5 or pre-tx T-score greater than -2.5 and less than -1 with a high pre-tx FRAX fracture probability AND patient has ANY of the following: a) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy, OR b) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 24 months lifetime total for parathyroid hormone analogs |

| | |
|---|---|
| **Other Criteria** | Patient has high Fracture Risk Assessment Tool (FRAX) fracture probability if the 10 year probability is either greater than or equal to 20 percent for any major osteoporotic fracture or greater than or equal to 3 percent for hip fracture. If glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture. |

# TYSABRI

## Products Affected

- Tysabri

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active Crohn's disease (new starts only): Patient has experienced an inadequate treatment response, intolerance or has a contraindication to at least one conventional therapy option (e.g., corticosteroids) AND one tumor necrosis factor (TNF) inhibitor indicated for Crohn's disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TYVASO

## Products Affected

- Tyvaso
- Tyvaso Refill Kit
- Tyvaso Starter Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (World Health Organization [WHO] Group 1) or pulmonary hypertension associated with interstitial lung disease (WHO Group 3) : the diagnosis was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# TYVASO DPI

## Products Affected

- Tyvaso Dpi Maintenance Kit
- Tyvaso Dpi Titration Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (World Health Organization [WHO] Group 1) or pulmonary hypertension associated with interstitial lung disease (WHO Group 3) : the diagnosis was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# TZIELD

## Products Affected

- Tzield

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the delay of Stage 3 type 1 diabetes (T1D): 1) the patient has a diagnosis of Stage 2 T1D that was confirmed by both of the following: a) at least two positive pancreatic islet cell autoantibodies AND b) dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) or alternative method if appropriate, AND 2) The clinical history of the patient does not suggest type 2 diabetes. |
| **Age Restrictions** | 8 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# UBRELVY

## Products Affected

- Ubrelvy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute treatment of migraine: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to at least one triptan 5-HT1 receptor agonist. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ULTOMIRIS

**Products Affected**

- Ultomiris INJ 1100MG/11ML, 300MG/3ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For paroxysmal nocturnal hemoglobinuria (PNH) (initial): 1) the diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by either: a) at least 5% PNH cells or b) at least 51% of GPI-AP deficient polymorphonuclear (PMN) cells AND 2) flow cytometry is used to demonstrate GPI-AP deficiency. For PNH (continuation of therapy): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) the patient has demonstrated a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels). For atypical hemolytic uremic syndrome: the disease is not caused by Shiga toxin-producing Escherichia coli. For neuromyelitis optica spectrum disorder (continuation): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) the pt has demonstrated a positive response to therapy (e.g., reduction in number of relapses). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | PNH, NMOSD - initial: 6 months, All other: Plan Year |
| **Other Criteria** | N/A |

# UPLIZNA

## Products Affected

- Uplizna

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# UPTRAVI

## Products Affected

- Uptravi
- Uptravi Titration Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# UZEDY

## Products Affected

- Uzedy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Tolerability with oral risperidone has been established. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VABOMERE

## Products Affected

- Vabomere

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | 14 days |
| **Other Criteria** | N/A |

# VABYSMO

## Products Affected

- Vabysmo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# VALCHLOR

## Products Affected

- Valchlor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Chronic or smoldering adult T-cell leukemia/lymphoma (ATLL), Stage 2 or higher mycosis fungoides (MF)/Sezary syndrome (SS), primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma, CD30-positive lymphomatoid papulosis (LyP), unifocal Langerhans cell histiocytosis (LCH) with isolated skin disease |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VALTOCO

## Products Affected

- Valtoco 10 Mg Dose
- Valtoco 15 Mg Dose
- Valtoco 20 Mg Dose
- Valtoco 5 Mg Dose

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VANFLYTA

## Products Affected

- Vanflyta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VECAMYL

## Products Affected

- Vecamyl

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Use in patients with coronary insufficiency, recent myocardial infarction, uremia, glaucoma, or organic pyloric stenosis. |
| **Required Medical Information** | For moderately severe to severe essential hypertension and uncomplicated cases of malignant hypertension, patient has a documented inadequate treatment response, intolerance, or contraindication to an adequate trial of one month of a two-drug combination from the preferred alternatives from the following classes: diuretics, angiotensin-converting enzyme inhibitors, angiotensin II receptor antagonists, beta-adrenergic blockers, calcium channel blockers. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VECTIBIX

## Products Affected

- Vectibix INJ 100MG/5ML, 400MG/20ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Appendiceal adenocarcinoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For colorectal cancer, patient meets both of the following: 1) Tumor is negative (wild-type) for RAS (KRAS and NRAS) mutations, and 2) Patient has not previously experienced clinical failure on cetuximab. For appendiceal adenocarcinoma: 1) tumor is BRAF V600E positive and 2) the requested drug will be used in combination with encorafenib. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VEGZELMA

**Products Affected**

- Vegzelma

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Ampullary adenocarcinoma, breast cancer, central nervous system (CNS) cancers, malignant pleural mesothelioma, malignant peritoneal mesothelioma, pericardial mesothelioma, tunica vaginalis testis mesothelioma, soft tissue sarcomas, uterine neoplasms, endometrial carcinoma, vulvar cancers, small bowel adenocarcinoma, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications except ophthalmic-related disorders: The patient had an intolerable adverse event to Zirabev and that adverse event was NOT attributed to the active ingredient as described in the prescribing information. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# VEKLURY

## Products Affected

- Veklury INJ 100MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in a non-hospitalized patient all of the following are met: 1) patient is at high risk for progression to severe COVID-19 (e.g., age 60 or older, body mass index [BMI] 30 or greater, hypertension, diabetes mellitus, chronic lung disease), including hospitalization and death, AND 2) treatment with the requested drug is initiated within 7 days of symptom onset. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 30 Days |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# VELCADE

## Products Affected

- Bortezomib INJ 1MG, 2.5MG, 3.5MG
- Velcade

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Systemic light chain amyloidosis, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, multicentric Castleman's disease, adult T-cell leukemia/lymphoma, acute lymphoblastic leukemia, Kaposi's sarcoma, Hodgkin lymphoma, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# VELSIPITY

## Products Affected

- Velsipity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active ulcerative colitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VENCLEXTA

## Products Affected

- Venclexta
- Venclexta Starting Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Mantle cell lymphoma, blastic plasmacytoid dendritic cell neoplasm (BPDCN), multiple myeloma, relapsed or refractory acute myeloid leukemia (AML), Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, relapsed or refractory systemic light chain amyloidosis with translocation t(11:14), myelodysplastic syndrome |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute myeloid leukemia (AML): 1) patient is 60 years of age or older, OR 2) patient is less than 60 years of age with unfavorable risk genetics and TP53-mutation, OR 3) patient has comorbidities that preclude use of intensive induction chemotherapy, OR 4) patient has relapsed or refractory disease. For blastic plasmacytoid dendritic cell neoplasm (BPDCN): 1) patient has systemic disease being treated with palliative intent, OR 2) patient has relapsed or refractory disease. For multiple myeloma: 1) the disease is relapsed or progressive, AND 2) the requested drug will be used in combination with dexamethasone, AND 3) patient has t(11:14) translocation. For Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma: 1) patient has previously treated disease that did not respond to primary therapy, OR 2) patient has progressive or relapsed disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VENTAVIS

## Products Affected

- Ventavis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# VEOPOZ

## Products Affected

- Veopoz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For CD55-deficient protein-losing enteropathy (PLE), initial: Patient has a confirmed biallelic CD55 loss-of-function mutation detected by genotype analysis. For CD55-deficient PLE, continuation: 1) There is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) Patient demonstrates a positive response to therapy (e.g., normalization of serum albumin, improvement in signs and symptoms of disease). |
| **Age Restrictions** | 1 year of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# VEOZAH

## Products Affected

- Veozah

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VERKAZIA

## Products Affected

- Verkazia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to an ophthalmic mast cell stabilizer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VERSACLOZ

## Products Affected

- Versacloz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | 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 experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VERZENIO

## Products Affected

- Verzenio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in combination with fulvestrant or an aromatase inhibitor, or as a single agent if progression on prior endocrine therapy and prior chemotherapy in the metastatic setting. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VEVYE

## Products Affected

- Vevye

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For signs and symptoms of dry eye disease (DED): 1) Patient has experienced an inadequate treatment response or intolerance to Restasis (cyclosporine 0.05 percent emulsion) AND 2) Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: Xiidra (lifitegrast), Miebo (perfluorohexyloctane). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VIBATIV AET

## Products Affected

- Vibativ INJ 750MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Use of intravenous unfractionated heparin sodium. |
| **Required Medical Information** | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. If culture shows susceptibility to vancomycin, the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to vancomycin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# VIBERZI

## Products Affected

- Viberzi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VICTOZA AET

## Products Affected

- Liraglutide
- Victoza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient meets both of the following: 1) The patient has a diagnosis of type 2 diabetes mellitus, AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to two of the following: Bydureon (exenatide), Byetta (exenatide), Trulicity (dulaglutide), Ozempic (semaglutide), Rybelsus (semaglutide). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VIEKIRA AET

## Products Affected

- Viekira Pak

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C) |
| **Required Medical Information** | For hepatitis C virus (HCV): infection confirmed by presence of HCV RNA in the serum prior to starting treatment. The patient must have a contraindication or intolerance to 2 of the following, if appropriate, based on current AASLD/IDSA guidance: Epclusa (velpatasvir and sofosbuvir), Harvoni (ledipasvir and sofosbuvir), Mavyret (glecaprevir and pibrentasvir), Vosevi (sofosbuvir, velpatasvir, and voxilaprevir). Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [CTP class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | For cirrhosis/post-liver transplant: up to 24 weeks. All others: up to 12 weeks. |
| **Other Criteria** | N/A |

# VIGABATRIN

## Products Affected

- Sabril
- Vigabatrin
- Vigadrone
- Vigpoder

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For complex partial seizures (i.e., focal impaired awareness seizures): patient has experienced an inadequate treatment response to at least two antiepileptic drugs for complex partial seizures (i.e., focal impaired awareness seizures). |
| **Age Restrictions** | Infantile Spasms: 1 month to 2 years of age. Complex partial seizures (i.e., focal impaired awareness seizures): 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VIGAFYDE

## Products Affected

- Vigafyde

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Infantile Spasms: 1 month to 2 years of age |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VIJOICE

## Products Affected

- Vijoice

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VILTEPSO

## Products Affected

- Viltepso

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VIMIZIM

## Products Affected

- Vimizim

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For mucopolysaccharidosis type IVA (MPS IVA, Morquio A syndrome): Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of N-acetylgalactosamine 6-sulfatase enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VITRAKVI

## Products Affected

- Vitrakvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, the disease is without a known acquired resistance mutation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VIVJOA

## Products Affected

- Vivjoa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | The patient is of reproductive potential. |
| **Required Medical Information** | To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in a patient with a history of RVVC: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to fluconazole AND 2) The requested drug will be used orally. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 weeks |
| **Other Criteria** | N/A |

# VIZIMPRO

## Products Affected

- Vizimpro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent non-small cell lung cancer (NSCLC). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced or metastatic, and 2) the patient has sensitizing EGFR mutation-positive disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VONJO

## Products Affected

- Vonjo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VORANIGO

## Products Affected

- Voranigo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VORICONAZOLE

## Products Affected

- Vfend SUSR
- Vfend IV
- Voriconazole INJ
- Voriconazole SUSR

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient will use the requested drug orally or intravenously. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# VOSEVI

## Products Affected

- Vosevi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C) |
| **Required Medical Information** | For hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD-IDSA guidance. |
| **Other Criteria** | N/A |

# VOTRIENT

## Products Affected

- Pazopanib Hydrochloride
- Votrient

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Thyroid carcinoma (follicular, papillary, Hurthle cell, or medullary), uterine sarcoma, chondrosarcoma, gastrointestinal stromal tumor |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For renal cell carcinoma: 1) The disease is advanced, relapsed, or stage IV, OR 2) the requested drug will be used for von Hippel-Lindau (VHL)-associated renal cell carcinoma. For gastrointestinal stromal tumor (GIST): the patients meets one of the following: 1) the disease is unresectable, recurrent/progressive, or metastatic AND the patient has failed an FDA-approved therapy (e.g., imatinib, sunitinib, regorafenib, ripretinib), 2) the requested drug will be used for unresectable succinate dehydrogenase (SDH)-deficient GIST, OR 3) the requested drug will be used for the palliation of symptoms if previously tolerated and effective. For soft tissue sarcoma (STS): The patient does not have an adipocytic soft tissue sarcoma. For uterine sarcoma: The disease is recurrent or metastatic. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VOWST

## Products Affected

- Vowst

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the prevention of recurrence of Clostridioides difficile infection (CDI): 1) The diagnosis of CDI has been confirmed by a positive stool test for C. difficile toxin, AND 2) The requested drug will be administered at least 48 hours after the last dose of antibiotics used for the treatment of recurrent CDI. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# VOXZOGO

## Products Affected

- Voxzogo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For achondroplasia with open epiphyses, initial: The diagnosis is confirmed by either of the following: 1) radiological findings of characteristic features consistent with the disease OR 2) genetic testing. For achondroplasia with open epiphyses, continuation of therapy: patient is experiencing improvement. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist, geneticist, neurologist, or skeletal dysplasia specialist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VOYDEYA

## Products Affected

- Voydeya

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For paroxysmal nocturnal hemoglobinuria (PNH) (initial): 1) the diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) AND 2) flow cytometry is used to demonstrate GPI-AP deficiency AND 3) the requested drug is being used as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH). For PNH (continuation): 1) there is no evidence of unacceptable toxicity or disease progression while on the current regimen AND 2) the patient has demonstrated a positive response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# VPRIV

## Products Affected

- Vpriv

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For type 1 Gaucher disease: Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VTAMA

## Products Affected

- Vtama

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For plaque psoriasis: The patient has experienced an inadequate treatment response or intolerance to at least one topical corticosteroid OR the patient has a contraindication that would prohibit a trial with topical corticosteroids. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VUITY

## Products Affected

- Vuity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of presbyopia, continuation: Patient experiences improvement from baseline presbyopia. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 2 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# VUMERITY

## Products Affected

- Vumerity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VYEPTI

## Products Affected

- Vyepti

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: Antiepileptic drugs (AEDs), Beta-adrenergic blocking agents, Antidepressants. For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug, and the patient had a reduction in migraine days per month from baseline. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 3 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# VYJUVEK

## Products Affected

- Vyjuvek

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will not be administered to wound(s) that are currently healed. |
| **Age Restrictions** | 6 months of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist or wound care specialist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# VYNDAMAX

## Products Affected

- Vyndamax

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cardiomyopathy of hereditary or wild-type transthyretin-mediated amyloidosis (ATTR-CM): Initiation: 1) patient exhibits clinical manifestation of disease (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema), AND 2) cardiac involvement was confirmed by echocardiography or cardiac magnetic resonance imaging (e.g., end-diastolic interventricular septal wall thickness exceeding 12 millimeters), AND 3) patient meets one of the following: a) if the request is for hereditary ATTR-CM the patient is positive for a mutation of the transthyretin (TTR) gene, b) if the request is for wild-type ATTR-CM the patient has transthyretin precursor proteins confirmed by testing. Continuation: patient demonstrates a beneficial response to therapy (e.g., slowing of clinical decline). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VYNDAQEL

## Products Affected

- Vyndaqel

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For cardiomyopathy of hereditary or wild-type transthyretin-mediated amyloidosis (ATTR-CM): Initiation: 1) patient exhibits clinical manifestation of disease (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema), AND 2) cardiac involvement was confirmed by echocardiography or cardiac magnetic resonance imaging (e.g., end-diastolic interventricular septal wall thickness exceeding 12 millimeters), AND 3) patient meets one of the following: a) if the request is for hereditary ATTR-CM the patient is positive for a mutation of the transthyretin (TTR) gene, b) if the request is for wild-type ATTR-CM the patient has transthyretin precursor proteins confirmed by testing. Continuation: patient demonstrates a beneficial response to therapy (e.g., slowing of clinical decline). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VYONDYS 53

## Products Affected

- Vyondys 53

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VYVGART

## Products Affected

- Vyvgart

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VYVGART HYTRULO

## Products Affected

- Vyvgart Hytrulo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# VYXEOS

## Products Affected

- Vyxeos

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Antecedent myelodysplastic syndrome/chronic myelomonocytic leukemia (MDS/CMML) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# WAINUA

## Products Affected

- Wainua

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For polyneuropathy of hereditary transthyretin (TTR)-mediated amyloidosis, initial therapy: Patient is positive for a mutation of the TTR gene and exhibits clinical manifestation of disease (for example, amyloid deposition in biopsy specimens, TTR protein variants in serum, progressive peripheral sensory-motor polyneuropathy). For polyneuropathy of hereditary TTR-mediated amyloidosis, continuation: Patient demonstrates a beneficial response to therapy (for example, improvement of neuropathy severity and rate of disease progression). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# WAKIX

## Products Affected

- Wakix

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of excessive daytime sleepiness in a patient with narcolepsy, initial request: 1) The diagnosis has been confirmed by sleep lab evaluation, AND 2) If the request is for an adult, the patient experienced an inadequate treatment response or intolerance to at least one CNS wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of CNS wakefulness promoting drugs (e.g., armodafinil, modafinil). For the treatment of cataplexy in a patient with narcolepsy, initial request: The diagnosis has been confirmed by sleep lab evaluation. For continuation of therapy: The patient has experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy. |
| **Age Restrictions** | Cataplexy: 18 years of age or older, Excessive Daytime Sleepiness: 6 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a sleep disorder specialist or neurologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# WELIREG

## Products Affected

- Welireg

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For advanced renal cell carcinoma (RCC): 1) patient previously received treatment with a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, AND 2) patient previously received treatment with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) [e.g., Cabometyx (cabozantinib), Inlyta (axitinib), Nexavar (sorafenib)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# WINLEVI

## Products Affected

- Winlevi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance or the patient has a contraindication to a generic acne product (e.g., topical clindamycin, topical erythromycin, topical retinoid, or oral isotretinoin). |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# WINREVAIR

## Products Affected

- Winrevair

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XALKORI

**Products Affected**

- Xalkori

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent non-small cell lung cancer (NSCLC), NSCLC with high-level MET amplification or MET exon 14 skipping mutation, symptomatic or relapsed/refractory anaplastic lymphoma kinase (ALK)-fusion positive Erdheim-Chester Disease, symptomatic or relapsed/refractory (ALK)-fusion positive Rosai-Dorfman Disease, (ALK)-fusion positive Langerhans Cell Histiocytosis. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For NSCLC, the requested drug is used in any of the following settings: 1) the patient has recurrent, advanced or metastatic ALK-positive NSCLC, OR 2) the patient has recurrent, advanced or metastatic ROS-1 positive NSCLC, OR 3) the patient has NSCLC with high-level MET amplification or MET exon 14 skipping mutation. For IMT, the disease is ALK-positive. For ALCL, the disease is relapsed or refractory and ALK-positive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XDEMVY

## Products Affected

- Xdemvy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XELJANZ

## Products Affected

- Xeljanz
- Xeljanz Xr

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active rheumatoid arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For active psoriatic arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]) AND 2) the requested drug is used in combination with a nonbiologic DMARD. For active ankylosing spondylitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For moderately to severely active ulcerative colitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Humira [adalimumab], Idacio [adalimumab-aacf]). For active polyarticular course juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |

| | |
|---|---|
| **Other Criteria** | N/A |

# XEMBIFY

**Products Affected**

- Xembify

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# XENLETA

## Products Affected

- Xenleta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility OR 2) local epidemiology and susceptibility patterns. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 7 days |
| **Other Criteria** | N/A |

# XENPOZYME

## Products Affected

- Xenpozyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acid sphingomyelinase deficiency (ASMD): The diagnosis was confirmed by an enzyme assay demonstrating a deficiency of acid sphingomyelinase (ASM) enzyme activity or by genetic testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XEOMIN

## Products Affected

- Xeomin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Cosmetic use. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XERMELO

## Products Affected

- Xermelo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XGEVA

## Products Affected

- Xgeva

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For hypercalcemia of malignancy: condition is refractory to intravenous (IV) bisphosphonate therapy or there is a clinical reason to avoid IV bisphosphonate therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# XHANCE MAPD

## Products Affected

- Xhance

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient has experienced an inadequate treatment response to generic fluticasone nasal spray. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XIAFLEX

## Products Affected

- Xiaflex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Cosmetic use (e.g., cellulite treatment) |
| **Required Medical Information** | For Dupuytren's contracture: 1) patient has a finger flexion contracture with a palpable cord in a metacarpophalangeal joint or a proximal interphalangeal joint, AND 2) the contracture is at least 20 degrees, AND 3) patient has a positive table top test, defined as the inability to simultaneously place the affected finger(s) and palm flat against a table. For Peyronie's disease: 1) the requested drug is not used to treat Peyronie's plaques that involve the penile urethra, AND 2) for initiation of therapy, patient has a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees with intact erectile function (with or without medication) at the start of therapy, AND 3) for continuation of therapy, the curvature deformity is 15 degrees or greater. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Dupuytren's contracture: 6 months. Peyronie's disease: 12 months. |
| **Other Criteria** | N/A |

# XIFAXAN

## Products Affected

- Xifaxan TABS 550MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For irritable bowel syndrome with diarrhea (IBS-D): 1) The patient has not previously received treatment with the requested drug OR 2) The patient has previously received treatment with the requested drug AND a) the patient is experiencing a recurrence of symptoms AND b) the patient has not already received an initial 14-day course of treatment and two additional 14-day courses of treatment with the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Reduction in risk of overt HE recurrence: 6 Months, IBS-D: 14 Days |
| **Other Criteria** | N/A |

# XIFAXAN200

## Products Affected

- Xifaxan TABS 200MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility OR 2) local epidemiology and susceptibility patterns. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 7 Days |
| **Other Criteria** | N/A |

# XIPERE

## Products Affected

- Xipere

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an optometrist or ophthalmologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# XOLAIR

## Products Affected

- Xolair

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderate to severe persistent asthma, initial therapy: 1) Patient has a positive skin test (or blood test) to at least one perennial aeroallergen, 2) Patient has baseline IgE level greater than or equal to 30 IU/mL, AND 3) Patient has inadequate asthma control despite current treatment with both of the following medications: a) Medium-to-high-dose inhaled corticosteroid, AND b) Additional controller (i.e., long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For moderate to severe persistent asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For chronic spontaneous urticaria (CSU), initial therapy: 1) Patient has been evaluated for other causes of urticaria, including bradykinin-related angioedema and IL-1-associated urticarial syndromes (e.g., auto-inflammatory disorders, urticarial vasculitis), 2) Patient has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks, AND 3) Patient remains symptomatic despite H1 antihistamine treatment. For CSU, continuation of therapy: Patient has experienced a benefit (e.g., improved symptoms) since initiation of therapy. For chronic rhinosinusitis with nasal polyps (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) Patient has experienced inadequate treatment response to Xhance (fluticasone). |
| **Age Restrictions** | CSU: 12 years of age or older. Asthma: 6 years of age or older. CRSwNP: 18 years of age or older. IgE-mediated food allergy: 1 year of age or older |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | CSU initial: 6 months, All others: Plan Year |
| **Other Criteria** | For IgE-mediated food allergy, initial therapy: Patient has baseline IgE level greater than or equal to 30 IU/mL. For IgE-mediated food allergy, continuation of therapy: Patient has experienced a benefit as evidenced by a decrease in hypersensitivity (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms) to food allergen. |

# XOLREMDI

## Products Affected

- Xolremdi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis), initial: 1) Diagnosis has been confirmed via testing to detect mutations in the CXCR4 gene AND 2) The patient exhibits at least one clinical manifestation of the disease (such as warts, hypogammaglobulinemia, infections, myelokathexis) AND 3) The patient has a confirmed low neutrophil count based on the reference laboratory range or current practice guidelines. For WHIM syndrome, continuation: The patient has demonstrated a positive response to therapy. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# XOSPATA

**Products Affected**

- Xospata

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FMS-like tyrosine kinase 3 (FLT3) rearrangement: the disease is in chronic or blast phase. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XPHOZAH

**Products Affected**

- Xphozah

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XPOVIO

## Products Affected

- Xpovio
- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Twice Weekly

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, high-grade B-cell lymphoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For multiple myeloma: Patient must have been treated with at least one prior therapy. For B-cell lymphomas: Patient must have been treated with at least two lines of systemic therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XTANDI

## Products Affected

- Xtandi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer: The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XURIDEN

## Products Affected

- Xuriden

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For orotic aciduria type 1 (OA1) (hereditary orotic aciduria): Diagnosis is confirmed by one of the following: 1) biochemical test detecting elevated levels of orotic acid in the urine or 2) genetic test showing mutations in the uridine monophosphate synthetase (UMPS) gene. For OA1, continuation: Patient's condition is stable or showing clinical improvement. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months, Continuation: Plan Year |
| **Other Criteria** | N/A |

# XYOSTED AET

**Products Affected**

- Xyosted

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Gender Dysphoria |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. Gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy. For all indications: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to a generic topical testosterone gel AND one of the following: generic testosterone enanthate or generic testosterone cypionate. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XYREM

## Products Affected

- Sodium Oxybate
- Xyrem

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of excessive daytime sleepiness in a patient with narcolepsy, initial request: 1) The diagnosis has been confirmed by sleep lab evaluation, AND 2) The patient meets one of the following criteria: a) if the patient is 17 years of age or younger, the patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate), OR has a contraindication that would prohibit a trial of central nervous system (CNS) stimulant drugs (e.g., amphetamine, dextroamphetamine, methylphenidate), b) If the patient is 18 years of age or older, the patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drugs (e.g., armodafinil, modafinil). For the treatment of cataplexy in a patient with narcolepsy, initial request: The diagnosis has been confirmed by sleep lab evaluation. If the request is for a continuation of therapy, then the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy. |
| **Age Restrictions** | 7 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a sleep disorder specialist or neurologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# XYWAV

## Products Affected

- Xywav

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of excessive daytime sleepiness in a patient (pt) with narcolepsy, initial request: 1) the diagnosis (dx) has been confirmed by sleep lab evaluation, AND 2) the pt meets one of the following criteria: a) If the pt is 17 years of age or younger, the pt has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate), OR has a contraindication that would prohibit a trial of CNS stimulant drugs (e.g., amphetamine, dextroamphetamine, methylphenidate), b) If the pt is 18 years of age or older, the pt has experienced an inadequate treatment response or intolerance to at least one CNS wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of CNS wakefulness promoting drugs (e.g., armodafinil, modafinil). For idiopathic hypersomnia the diagnosis has been confirmed by ALL of the following: 1) pt has experienced lapses into sleep or an irrepressible need to sleep during daytime, on a daily basis, for at least 3 months, AND 2) insufficient sleep syndrome is confirmed absent, AND 3) cataplexy is absent, AND 4) fewer than 2 sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs, if the rapid eye movement latency on an overnight sleep study was less than or equal to 15 minutes, AND 5) average sleep latency of less than or equal to 8 minutes on Multiple Sleep Latency Test or total 24-hour sleep time is greater than or equal to 11 hours, AND 6) another condition (sleep disorder, medical or psychiatric disorder, or drug/medication use) does not better explain the hypersomnolence and test results. |
| **Age Restrictions** | Narcolepsy: 7 years of age or older, Idiopathic hypersomnia: 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a sleep disorder specialist or neurologist |

| | |
|---|---|
| **Coverage Duration** | Plan Year |
| **Other Criteria** | For the treatment of cataplexy in a pt with narcolepsy, initial request: the dx has been confirmed by sleep lab evaluation. For narcolepsy, continuation of therapy: the pt has experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy. For idiopathic hypersomnia, continuation of therapy: the pt has experienced a decrease in daytime sleepiness from baseline. |

# YCANTH

## Products Affected

- Ycanth

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# YERVOY

## Products Affected

- Yervoy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# YONDELIS

**Products Affected**

- Yondelis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Soft tissue sarcoma (extremity/body wall or head/neck, retroperitoneal/intra-abdominal, rhabdomyosarcoma, solitary fibrous tumor) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an Oncologist or Hematologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# YONSA

## Products Affected

- Yonsa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# YUPELRI AET

## Products Affected

- Yupelri

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following: Breo Ellipta (fluticasone/vilanterol), fluticasone/salmeterol, Incruse Ellipta (umeclidinium), Anoro Ellipta (umeclidinium/vilanterol), Bevespi (glycopyrrolate/formoterol), Serevent Diskus (salmeterol), Trelegy Ellipta (fluticasone/umeclidinium/vilanterol), Wixela. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# ZALTRAP

## Products Affected

- Zaltrap

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Unresectable colorectal cancer. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For advanced, unresectable, or metastatic colorectal cancer (including appendiceal adenocarcinoma): the requested drug will be used in combination with FOLFIRI or irinotecan. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZARXIO

## Products Affected

- Zarxio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Neutropenia in myelodysplastic syndromes (MDS), agranulocytosis, neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia, neutropenia related to renal transplant, hematopoietic syndrome of acute radiation syndrome |
| **Exclusion Criteria** | Use of the requested product within 24 hours prior to or following chemotherapy. |
| **Required Medical Information** | For prophylaxis or treatment of myelosuppressive chemotherapy-induced febrile neutropenia (FN) patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, and 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

# ZAVZPRET

## Products Affected

- Zavzpret

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For acute migraine: 1) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to at least one triptan 5-HT1 receptor agonist AND 2) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to Nurtec ODT (rimegepant) OR Ubrelvy (ubrogepant). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZEGERID CAPSULE AET

**Products Affected**

- Zegerid CAPS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has an intolerance or a contraindication to OR has experienced an inadequate treatment response to a one-month trial of TWO of the following formulary generic proton pump inhibitors (PPIs): lansoprazole, omeprazole, omeprazole/bicarbonate, pantoprazole, esomeprazole sodium, or esomeprazole magnesium. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZEGERID SUSPENSION AET

## Products Affected

- Zegerid PACK

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications except the reduction of risk of upper GI bleed in critically ill patients: the patient has an intolerance or a contraindication to OR has experienced an inadequate treatment response to a one-month trial of TWO of the following formulary generic proton pump inhibitors (PPIs): lansoprazole, omeprazole, omeprazole/bicarbonate, pantoprazole, esomeprazole sodium, or esomeprazole magnesium. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZEJULA

## Products Affected

- Zejula TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Uterine leiomyosarcoma |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy AND 2) the patient has BRCA-altered disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZELBORAF

## Products Affected

- Zelboraf

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Non-small cell lung cancer, hairy cell leukemia, thyroid carcinoma (i.e., papillary carcinoma, follicular carcinoma, and Hurthle cell carcinoma), central nervous system cancer (i.e., glioma, astrocytoma, glioblastoma, pediatric diffuse high-grade glioma), adjuvant systemic therapy for cutaneous melanoma, Langerhans cell histiocytosis. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For central nervous system (CNS) cancer (i.e., glioma, astrocytoma, glioblastoma, pediatric diffuse high-grade glioma): 1) The tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used in combination with cobimetinib OR the requested drug is being used for the treatment of pediatric diffuse high-grade glioma. For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) the requested drug will be used as a single agent, or in combination with cobimetinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, or b) adjuvant systemic therapy. For Erdheim-Chester Disease and Langerhans Cell Histiocytosis: Tumor is positive for BRAF V600 mutation. For non-small cell lung cancer: 1) The tumor is positive for the BRAF V600E mutation, AND 2) The patient has recurrent, advanced, or metastatic disease. For papillary, follicular, and hurthle cell thyroid carcinoma: 1) The tumor is positive for BRAF mutation, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZEMDRI

## Products Affected

- Zemdri

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | 14 days |
| **Other Criteria** | N/A |

# ZEPATIER AET

**Products Affected**

- Zepatier

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Hepatitis C genotype 3 infection |
| **Exclusion Criteria** | Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C) |
| **Required Medical Information** | For hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. The patient must have a contraindication or intolerance to 2 of the following, if appropriate, based on current AASLD/IDSA guidance: Epclusa (velpatasvir and sofosbuvir), Harvoni (ledipasvir and sofosbuvir), Mavyret (glecaprevir and pibrentasvir), Vosevi (sofosbuvir, velpatasvir, and voxilaprevir) AND the criteria will be applied consistent with current AASLD-IDSA guidance. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions (e.g., NS5A polymorphisms) where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD-IDSA guidance. |
| **Other Criteria** | N/A |

# ZEPOSIA

## Products Affected

- Zeposia
- Zeposia 7-day Starter Pack
- Zeposia Starter Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For moderately to severely active ulcerative colitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one conventional therapy (e.g., corticosteroids). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZEPZELCA

## Products Affected

- Zepzelca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Relapsed small cell lung cancer, primary progressive small cell lung cancer. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For small cell lung cancer: the requested medication will be used as a single agent in one of the following settings: 1) the disease has relapsed following complete or partial response or stable disease with initial treatment, 2) the patient has primary progressive disease, or 3) the patient has metastatic disease following disease progression on or after platinum-based chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZILBRYSQ

## Products Affected

- Zilbrysq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZILXI

## Products Affected

- Zilxi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic topical metronidazole or topical azelaic acid 15 percent. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZINPLAVA

## Products Affected

- Zinplava

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 1 year of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# ZIRABEV

## Products Affected

- Zirabev

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Ampullary adenocarcinoma, breast cancer, central nervous system (CNS) cancers, malignant pleural mesothelioma, malignant peritoneal mesothelioma, pericardial mesothelioma, tunica vaginalis testis mesothelioma, soft tissue sarcomas, uterine neoplasms, endometrial carcinoma, vulvar cancers, small bowel adenocarcinoma, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# ZOKINVY

## Products Affected

- Zokinvy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For Hutchinson-Gilford Progeria Syndrome and for processing-deficient Progeroid Laminopathy with heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations: 1) diagnosis is confirmed by genetic testing AND 2) patient has a body surface area of 0.39 meters squared or above. |
| **Age Restrictions** | 12 months of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZOLINZA

## Products Affected

- Zolinza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Mycosis fungoides (MF)/Sezary syndrome (SS) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZOLPIDEM CAP

## Products Affected

- Zolpidem Tartrate CAPS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For insomnia: The patient has experienced an inadequate treatment response or intolerance to zolpidem immediate-release tablets. |
| **Age Restrictions** | Less than 65 years of age |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZONISADE

## Products Affected

- Zonisade

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For adjunctive treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| **Age Restrictions** | 16 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZORBTIVE

## Products Affected

- Zorbtive

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, gastrointestinal surgeon, or nutritional support specialist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZORYVE

## Products Affected

- Zoryve CREA 0.3%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For plaque psoriasis: The patient has experienced an inadequate treatment response or intolerance to at least one topical corticosteroid OR the patient has a contraindication that would prohibit a trial with topical corticosteroids. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZORYVE 0.15 PERCENT CREAM

**Products Affected**

- Zoryve CREA 0.15%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For mild to moderate atopic dermatitis, the patient meets either of the following criteria: 1) If the requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds), the patient has experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor OR 2) If the requested drug is being prescribed for use on non-sensitive (or remaining) skin areas, the patient has experienced an inadequate treatment response, intolerance, or contraindication to a medium or higher potency topical corticosteroid or a topical calcineurin inhibitor. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZORYVE FOAM

## Products Affected

- Zoryve FOAM

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For seborrheic dermatitis: If the patient is 12 years of age or older, the patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to topical ketoconazole. |
| **Age Restrictions** | 9 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZTALMY

## Products Affected

- Ztalmy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZTLIDO AET

## Products Affected

- Ztlido

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Pain associated with diabetic neuropathy, pain associated with cancer-related neuropathy (including treatment-related neuropathy [e.g., neuropathy associated with radiation treatment or chemotherapy]). |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For all indications: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to generic lidocaine patches. For post-herpetic neuralgia (PHN): patient has experienced an inadequate treatment response to one month of gabapentin or has an intolerance or contraindication to gabapentin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZURZUVAE

## Products Affected

- Zurzuvae

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the treatment of postpartum depression (PPD): diagnosis was confirmed using standardized rating scales that reliably measure depressive symptoms (e.g., Hamilton Depression Rating Scale [HDRS], Edinburgh Postnatal Depression Scale [EPDS], Patient Health Questionnaire 9 [PHQ9], Montgomery-Asberg Depression Rating Scale [MADRS], Beck's Depression Inventory [BDI], etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |

# ZYDELIG

## Products Affected

- Zydelig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Small lymphocytic lymphoma (SLL) |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For CLL/SLL: the requested drug is used as second-line or subsequent therapy |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZYKADIA

## Products Affected

- Zykadia TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Recurrent ALK-positive non-small cell lung cancer (NSCLC), recurrent, advanced, or metastatic ROS1-positive NSCLC, inflammatory myofibroblastic tumor (IMT), brain metastases from NSCLC. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For NSCLC: the patient has recurrent, advanced, or metastatic ALK-positive or ROS1-positive disease. For inflammatory myofibroblastic tumor: the disease is ALK-positive. For brain metastases from NSCLC: the patient has ALK-positive NSCLC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZYMFENTRA AET

## Products Affected

- Zymfentra 2-pen
- Zymfentra 2-syringe

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZYNLONTA

**Products Affected**

- Zynlonta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically accepted Indications. |
| **Off-Label Uses** | Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specified) and histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma. |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The requested drug will be used as second-line or subsequent therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZYNYZ

**Products Affected**

- Zynyz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# ZYPREXA RELPREVV

## Products Affected

- Zyprexa Relprevv

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Tolerability with oral olanzapine has been established. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |

# PART B VERSUS PART D

## Products Affected

- Abelcet
- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Adriamycin INJ 50MG
- Akynzeo CAPS
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Alkeran TABS
- Ambisome
- Amphotericin B INJ
- Amphotericin B Liposome
- Anzemet TABS 50MG
- Aprepitant CAPS
- Astagraf XL
- Atgam
- Azasan
- Azathioprine INJ
- Azathioprine TABS
- Baclofen INJ 20000MCG/20ML, 40MG/20ML, 500MCG/ML, 50MCG/ML
- Bleomycin Sulfate INJ
- Budesonide SUSP
- Cellcept
- Cellcept Intravenous
- Cladribine
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix 6/5
- Clinimix 8/10
- Clinimix 8/14
- Clinimix E 2.75%/dextrose 5% INJ 570MG/100ML; 316MG/100ML; 33MG/100ML; 5GM/100ML; 515MG/100ML; 132MG/100ML; 165MG/100ML; 201MG/100ML; 159MG/100ML; 51MG/100ML; 110MG/100ML; 454MG/100ML; 154MG/100ML; 261MG/100ML; 187MG/100ML; 138MG/100ML; 217MG/100ML; 112MG/100ML; 116MG/100ML; 50MG/100ML; 11MG/100ML; 160MG/100ML
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Clinimix E 8/10
- Clinimix E 8/14
- Clinisol Sf 15%
- Clinolipid
- Cromolyn Sodium NEBU
- Cyclosporine CAPS
- Cyclosporine INJ
- Cyclosporine Modified
- Cytarabine INJ 100MG/ML
- Cytarabine Aqueous
- Deferoxamine Mesylate
- Depo-medrol
- Desferal INJ 500MG
- Dextrose 25% INJ 250MG/ML
- Dextrose 50%
- Dextrose 70%
- Dilaudid INJ 0.2MG/ML, 1MG/ML, 2MG/ML
- Dobutamine Hcl INJ 250MG/20ML
- Dobutamine Hcl/d5w INJ 5%; 1MG/ML
- Dobutamine Hydrochloride/dextrose 5%
- Dopamine Hydrochloride INJ
- Dopamine Hydrochloride/dextrose
- Dopamine/d5w INJ 5%; 3.2MG/ML

- Doxorubicin Hcl INJ 50MG
- Doxorubicin Hydrochloride INJ 10MG, 200MG/100ML
- Duopa
- Duramorph
- Emend CAPS 80MG
- Emend SUSR
- Emend Tripack
- Engerix-b
- Envarsus Xr
- Epoprostenol Sodium
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Fentanyl Citrate INJ 1000MCG/20ML, 100MCG/2ML, 2500MCG/50ML, 250MCG/5ML, 500MCG/10ML, 50MCG/ML
- Fiasp Pumpcart
- Flolan
- Fluorouracil INJ 1GM/20ML, 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Gablofen
- Gamastan
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Hepatamine INJ 62MEQ/L; 770MG/100ML; 600MG/100ML; 3MEQ/L; 20MG/100ML; 900MG/100ML; 240MG/100ML; 900MG/100ML; 1100MG/100ML; 610MG/100ML; 100MG/100ML; 100MG/100ML; 115MG/100ML; 800MG/100ML; 500MG/100ML; 450MG/100ML; 66MG/100ML; 840MG/100ML
- Heplisav-b
- Humulin R U-500 (concentrated)
- Hydromorphone Hcl INJ 10MG/ML, 1MG/ML, 4MG/ML
- Hydromorphone Hydrochloride INJ 0.25MG/0.5ML, 1MG/ML, 2MG/ML, 4MG/ML, 50MG/5ML
- Hyperlyte-cr
- Imovax Rabies (h.d.c.v.)
- Imuran TABS
- Infumorph 200
- Infumorph 500
- Intralipid INJ 20GM/100ML, 30GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Isolyte-s INJ 27MEQ/L; 98MEQ/L; 23MEQ/L; 3MEQ/L; 5MEQ/L; 140MEQ/L
- Isolyte-s Ph 7.4
- Jynneos
- Kabiven
- Khapzory
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Medrol TABS 16MG, 2MG, 4MG, 8MG
- Melphalan
- Methylprednisolone TABS
- Methylprednisolone Acetate INJ 40MG/ML, 80MG/ML
- Methylprednisolone Sodium Succinate
- Methylprednisolone Sodiumsuccinate INJ 40MG
- Millipred TABS
- Milrinone Lactate INJ 10MG/10ML, 20MG/20ML, 50MG/50ML
- Milrinone Lactate In Dextrose
- Mitigo
- Morphine Sulfate INJ 0.5MG/ML, 10MG/ML, 1MG/ML, 2MG/ML, 4MG/ML, 50MG/ML, 5MG/ML, 8MG/ML
- Morphine Sulfate/sodium Chloride INJ 1MG/ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil INJ
- Mycophenolate Mofetil SUSR

- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Myfortic
- Myhibbin
- Nebupent
- Neoral
- Nulojix
- Nutrilipid
- Omegaven
- Ondansetron Hcl SOLN
- Ondansetron Hcl TABS 24MG
- Ondansetron Hydrochloride TABS
- Ondansetron Odt
- Orapred Odt
- Pediapred SOLN
- Pentamidine Isethionate INHALATION SOLR
- Perikabiven
- Plenamine INJ 147.4MEQ/L; 2.17GM/100ML; 1.47GM/100ML; 434MG/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 749MG/100ML; 1.04GM/100ML; 1.18GM/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 592MG/100ML; 749MG/100ML; 250MG/100ML; 39MG/100ML; 960MG/100ML
- Prednisolone SOLN
- Prednisolone TABS
- Prednisolone Sodium Phosphate ORAL SOLN 10MG/5ML, 15MG/5ML, 20MG/5ML, 25MG/5ML, 5MG/5ML
- Prednisolone Sodium Phosphate Odt
- Prednisone SOLN
- Prednisone TABS 10MG, 1MG, 2.5MG, 20MG, 50MG, 5MG
- Prednisone Intensol
- Prehevbrio
- Premasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML
- Prialt
- Prograf
- Prosol
- Pulmicort
- Rabavert
- Rapamune SOLN
- Rapamune TABS 1MG, 2MG
- Rayos
- Recombivax Hb
- Sandimmune CAPS 100MG, 25MG
- Sandimmune INJ
- Sandimmune SOLN
- Simulect
- Sirolimus SOLN
- Sirolimus TABS
- Smoflipid
- Solu-medrol INJ 1000MG, 125MG, 2GM, 40MG, 500MG
- Tacrolimus CAPS
- Thymoglobulin
- Tpn Electrolytes INJ 29.5MEQ/20ML; 4.5MEQ/20ML; 35MEQ/20ML; 5MEQ/20ML; 20MEQ/20ML; 35MEQ/20ML
- Travasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 500MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML

- Trophamine INJ 0.54GM/100ML; 1.2GM/100ML; 0.32GM/100ML; 0; 0; 0.5GM/100ML; 0.36GM/100ML; 0.48GM/100ML; 0.82GM/100ML; 1.4GM/100ML; 1.2GM/100ML; 0.34GM/100ML; 0.48GM/100ML; 0.68GM/100ML; 0.38GM/100ML; 5MEQ/L; 0.025GM/100ML; 0.42GM/100ML; 0.2GM/100ML; 0.24GM/100ML; 0.78GM/100ML
- Varubi TBPK
- Veletri
- Vinblastine Sulfate INJ 1MG/ML
- Vincasar Pfs
- Vincristine Sulfate INJ 1MG/ML
- Zortress
- Zulresso

## Details

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

# INDEX

*A*

***B***

## *C*

***D***

***E***

***F***

***G***



***H***

***I***

***J***



***K***



***L***

***M***

***N***

## *O*

***P***

## *Q*



## *R*

## *S*

***T***

## *U*



## *V*

## *W*



## *X*



## *Y*

## *Z*